A GUIDE FOR THE

PREPARATION OF RADIOACTIVE

MATERIAL LICENSE APPLICATIONS

FOR MEDICAL PROGRAMS

Radiation Health & Toxic Agent Branch
Cabinet for Health Services
275 East Main Street
Frankfort, Kentucky 40621

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EXHIBITS

I. INTRODUCTION

This guide is intended to provide assistance in the preparation of an application for a specific radioactive material license for possession and use of radioactive material for use in or on human beings.

Usually a single radioactive material license is issued to cover an institution's entire radioisotope program, other than teletherapy. Separate licenses are not issued to different departments of a medical institution, nor are they issued to individuals associated with the hospital.

This guide is intended only for general guidance in preparation of the license application and should not be considered a substitute for the applicant's careful safety evaluation of the proposed use of radiopharmaceuticals and sealed sources. The applicant must ensure that the application correctly and adequately describes the radiation safety measures and procedures to be followed to provide adequate protection.

II. FEES

The applicant should refer to 902 KAR 100:012, Fee Schedule, to determine what fees, if any, should accompany the application. Currently, the fee for a radioactive material license authorizing human use is $450.00. No action will be taken on applications filed without the proper fee. Checks should be make payable to the Kentucky State Treasurer. Payment of an annual renewal fee is required to renew the license.

A fee is also required when submitting an amendment application to change an existing license, unless the change is the result of a request by Radiation Health. The current amendment fee is $75.00 and must accompany the amendment application.

III. FILING AN APPLICATION

An initial application for a license must be filed on Form RPS-7 (Exhibit 1), "Application for Radioactive Material License" and should contain all information specified in the application form. Space provided on the form is limited and additional sheets should be attached as necessary. All items must be described in sufficient detail for the agency to evaluate the radiation safety program.

Two copies of the application should be prepared, each signed and dated in Item 15 by a representative of the institution's management.

The licensee must maintain one (1) copy and will be required to follow the statements set forth in the application, when the license has been issued. The original should be mailed to the Radiation Health and Toxic Agent Branch, Cabinet for Health Services, Mail Stop HS 2E-D, 275 East Main Street, Frankfort, Kentucky 40621.

IV. APPLICABLE REGULATIONS

In addition to 902 KAR 100:073, other regulations pertaining to the medical use of radioactive material are found in:

902 KAR 100:010	Definitions
902 KAR 100:012	Fees
902 KAR 100:015	General Requirements
902 KAR 100:019	Standards for Protection Against Radiation
902 KAR 100:021	Disposal of Radioactive Material
902 KAR 100:040	General Provisions for Specific Licenses
902 KAR 100:042	Decommissioning and Financial Surety
902 KAR 100:060	Leak Testing
902 KAR 100:070	Transportation of Radioactive Material
902 KAR 100:165	Notices, Reports, and Instructions to Employees

V. CONTENTS OF AN APPLICATION

Item 1- Applicant's Name and Mailing Address: The applicant must be specified by name and mailing address. For a private practice license, enter the name of the physician or partnership.

Item 2 – Street Address(es) Where Radioactive Material Will be Used: List the address(es) and location(s) where radioactive material will be used or stored if other than the address stated in Item 1. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use. The actual location(s) of use must be listed. For example, a post office box number may be suitable for Item 1, but this address does not describe the location of use.

Items 3 and 4 – Self Explanatory

Item 5 – Individual User(s): List the names of all persons who will use, supervise, or direct the use of radioactive material. This list should include the physicians who supervise other physicians in training, and/or who direct technologists or other paramedical personnel who use radioactive material for human or non-human use. Non-physicians may be authorized to use radioactive material for non-human use (e.g., instrument calibration).

Authorized physician-users have the following responsibilities:

a. The approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources.

b. The prescription of the radiopharmaceutical or source of radiation and amount or dose to be administered.

c. The determination of the route of administration.

d. The interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

Items a through d may be delegated to physicians who are in training under the supervision of authorized physician users except for a private practice license. ("Supervision" means the named user has adequately instructed the physicians in training in the specific use and has ascertained they are receiving training in the safe use of these materials. It also means that the user periodically reviews the work of those supervised and assures that proper records are kept. It does not mean the named user is present for each radiopharmaceutical administration.)

Properly trained technicians, technologist, or other paramedical personnel under an authorized user's direction may be delegated the following activities:

a. The preparation and quality control testing of radiopharmaceuticals and sources of radiation.

b. The measurement of radiopharmaceutical dose prior to administration.

c. The use of appropriate instrumentation for the collection of data to be used by the physician.

d. The administration of radiopharmaceuticals and radiation from radioisotopic sources to patients, if permitted under applicable Federal, State, or local laws.

Item 6 – Radiation Protection Officer: State the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation safety program. If the radiation safety officer (RSO) is not one of the proposed authorized users, submit a complete description of the individuals training and experience using Exhibit 2. The RSO should be a full-time employee of the licensee. **EVEN IF THE LICENSEE EMPLOYS A CONSULTANT TO ASSIST THE RSO, THE LICENSEE IS STILL RESPONSIBLE FOR THE RADIATION SAFETY PROGRAMS AS REQUIRED BY THE LICENSE.**

Item 7 – Licensed Material: 902 KAR 100:073, Sections 29 and 31 define uses of radiopharmaceuticals in diagnostic and imaging. You may list sections for these radiopharmaceuticals. For radioactive materials not covered in these sections, list each radionuclide to be used, the chemical and physical form, and the maximum quantity in millicuries.

For sealed sources list the manufacture's name, model number, and activity in millicuries. Certain radioactive material sources used for calibration and reference standards are authorized by regulation 902 KAR 100:073, Section 18, and should not be listed.

Describe the intended use for each radionuclide and form listed.

Item 8 – Radiation Detection Instruments: Complete the form contained in Appendix C listing the instrumentation to be available and submit as an attachment to the application. Instruments generally required in a typical nuclear medicine laboratory are:

A. Survey Instruments

(1) A low-level survey meter, with a thin window of 2 mg/cm^2, capable of detecting 0.1 milliroentgen per hour to perform contamination surveys.

(2) A high-level survey meter capable of reading up to 1 roentgen per hour to measure radiation exposure rates that may exist in the vicinity of Mo-99 /Tc-99m generators and therapeutic quantities of radioactive material.

B. Dose calibrators and other instruments to assay radiopharmaceuticals.

C. Instruments used for diagnostic procedures in nuclear medicine (e.g., gamma camera, thyroid probe, well counter, scintillation counter for in vitro studies).

D. If you are transporting imaging equipment as part of a mobile nuclear medicine service, describe your procedure for checking the equipment to ensure it has not been damaged in transit. See Appendix P.

E. Other pertinent instrumentation (e.g., liquid scintillation counter, area monitor).

Item 9- Calibration: Complete the appropriate portion of the form contained in Appendix D and submit as an attachment to the application for each of the following:

A. Survey Instruments. Appendix D, Part A.

B. Dose Calibrator. Appendix D, Part B.

C. Instruments Used for Diagnostic Purposes. Appendix D, Part B.

Item 10 - Personnel Monitoring Devices: Specify the type of personnel monitoring device(s) that will be used (i.e. whole body film badges, ring badges, or thermoluminescense dosimeters) and the names and addresses of the suppliers that may be used. The frequency of change of personnel monitoring devices should be specified. See Appendix Q.

Item 11 - Facilities and Equipment: Describe the available facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) at each location where radioactive material will be used. Include a description of the area(s) assigned for receipt, storage (including waste), preparation, and measurement of radioactive material.

Submit a detailed diagram of the facility, indicating the type, dimensions, position, and thickness of shielding that will be used for:

A. Use and storage of Tc-99m generators.

B. Storage of radiopharmaceuticals (refrigerated and non-refrigerated).

C. Storage of radioactive waste, including decay-in-storage prior to disposal of non-radioactive waste. (This area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste. If this area is located outside your department, describe how the material will be secured. Confirm that this area will be surveyed at least weekly.)

D. Preparation and dispensing of kit radiopharmaceuticals (e.g., lead glass L-block).

Identify adjacent areas across the walls from use and storage locations, and show that adequate steps have been taken to ensure that radiation levels in unrestricted areas do not exceed the limits specified in 902 KAR 100:019, Section 10.

Shielding requirements for the walls, floor, and ceiling should be evaluated for each nuclear medicine room based on total workload (in mCi/week), the energy of radiation, and the presence of patients with activity in the room. Adequate distances should be allowed between technologists and patients being scanned or imaged.

If Xe-133 is to be used, submit a version of your facility diagram that specifies the location and the measured airflow rate of each air exhaust vent and each air supply vent in areas where Xe-133 will be used or stored. (Appendix M describes additional information required for the use of xenon.)

For other facilities in which radioactive material may become airborne, include schematic descriptions of the ventilation system in the diagrams with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Draw diagrams to a specified scale, or indicate dimensions.

Item 12 - Radiation Protection Program:

A. Radiation Safety Committee/Radiation Safety Officer.

Describe your Radiation Safety Committee Charter and Radiation Safety Officer delegation of authority. A Radiation Safety Committee must be established by each medical institution licensee (see 902 KAR 100:073, Section 6) unless the application is only for devices listed in 902 KAR 100:073, Section 39 (such institutions will be exempted by license condition). If you are not an institution, you only need to submit the Radiation Safety Officer delegation of authority. See Appendix B.

B. ALARA Program.

Each radiation safety program should have an ALARA program (See 902 KAR 100:073, Section 4). Submit an ALARA program. Appendix 0 is a typical ALARA program.

C. Personnel Training Program.

Radiation workers (e.g. technologists) must receive instruction as specified in 902 KAR 100:165, Section 2. Note that many of these items pertain to circumstances at a particular institution; therefore, it may not be assumed that this instruction has been adequately covered by prior occupational training, Board certification, etc. Outline and submit the program for providing the necessary instruction. Appendix N is a typical training program.

Ancillary personnel (e.g., clerical, nursing, housekeeping, security personnel) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions.

Describe the training that will be provided to all personnel who work with, or in the vicinity of, radioactive materials. Appendix N contains an example of a typical personnel training program.

D. Leak Test

Submit your procedure for leak testing sealed sources. See Appendix R.

E. Procedures for Ordering and Receiving Radioactive Material.

Describe procedures for ordering radioactive material, for receiving material during off duty hours, and for notifying responsible persons upon receipt of radioactive material. These procedures should be adequate to ensure that possession limits are not exceeded, that radioactive material ordered for human use is adequately verified upon receipt and checked before use, that radioactive material is secured at all times against unauthorized removal, and that radiation levels in unrestricted areas do not exceed the limits specified in 902 KAR 100:019, Section 10.

Security personnel, nursing personnel, or anyone else who may receive packages during off duty hours should be issued written instructions as to procedures to be followed for (a) receiving, examining, and securing packages and (b) notifying specific personnel (including names and telephone numbers of persons to be contacted) if the package is found or suspected to be leaking and the immediate steps to be taken to prevent spread of contamination.

Appendix E to this guide contains sample procedures and instructions for ordering and receiving packages containing radioactive material. Attach a copy of your procedures.

F. Procedures for Safely Opening Packages Containing Radioactive Material.

Although 902 KAR 100:019, Section 28 (2) exempts certain packages from immediate monitoring, Section 28 (5) requires that each licensee establish procedures for safely opening all packages containing licensed material.

Describe your procedures for examining incoming packages for leakage, contamination, or damage, and for compliance with 902 KAR 100:019. Monitoring should be performed as soon as practicable after receipt of the package of radioactive material. The procedures may vary depending on the quantity of radioactive material received but should, at a minimum, include instructions for (a) surveying packages, (b) wearing gloves while opening packages, (c) checking packing material for contamination after opening, and (d) verifying package contents.

Appendix F to this guide contains a description of an acceptable procedure for safety opening packages.

G. General Rules for the Safe Use of Radioactive Material.

Describe the general instructions to be followed by physicians, radiopharmacists, and technologists while working with radioactive material. The instructions should:

1. Outline control procedures for obtaining permission to use radioactive material at the institution.

2. Explain what laboratory apparel to wear and what equipment to use (e.g., wear laboratory coats and disposable gloves, and use trays and remote handling devices).

3. Prescribe limitations and conditions for handling liquid or loose radioactive materials and the laboratory equipment to be used in working with them. For example, specify which materials and operations should be confined to radiochemical fume hoods or glove boxes.

4. Specify the shielding or remote handling equipment to be used when hard beta and/or gamma-emitting materials are handled. Preparation of radiopharmaceuticals from reagent kits should always be done behind shielding and within appropriate hoods or enclosures. Syringe shields should be used for the routine preparation and administration of patient doses, except on the rare occasions where difficulties in properly administering the dose to the patient would warrant expedited use of lighter syringes. Even in these cases, syringes with the best possible finger protection or remote delivery of the dose (e.g., through use of a butterfly valve) should be used.

5. Give instructions for preparation and assay of patient doses, including instructions to check each therapy dose against the ordering physician's written request.

6. Give instructions concerning movement of material between rooms, in halls, or in corridors, if applicable.

7. Explain requirements for storage of material, labeling of containers, and identification of areas where radioactive material is used. Describe the shielding used for areas where large amounts of radioactive material are stored.

8. Specify personnel monitoring devices to be used, were to obtain them, procedures for properly turning in personnel monitoring devices for processing at appropriate intervals, and instructions for recording exposure results. Also describe where personnel monitoring devices and control dosimeters will be stored to ensure accuracy in monitoring employee occupational exposures and to avoid inadvertent exposure of the devices when they are not being worn.

9. Describe waste disposal procedures to be followed for each type of waste (e.g., liquids, gases, solids, long-lived, short-lived). Properly shielded waste receptacles should be employed for used syringes and other radioactive wastes.

10. Describe contamination control procedures, including (1) prohibitions against smoking. eating, drinking, or applying cosmetics in restricted areas, (2) prohibition against storing food, beverages, and personal effects with radioactive material, and (3) instructions for individuals who prepare and administer doses of radiopharmaceuticals to monitor their hands after each procedure and at the end of the day.

    For certain programs, Appendix G to this guide contains an acceptable set of laboratory rules for the safe use of radioactive material.

H. Unit Dosage Records

Submit your procedure for keeping records of unit dosage use. See Appendix S.1.

I. Multidose Vial Records

Submit your procedure for keeping records of multidose vial use. See Appendix S.2.

J. Molybdenum Concentration Records

Submit your procedure for measuring and recording molybdenum concentration. See Appendix S.3.

K. Implant Source Use Records

Submit your procedure for keeping an inventory of implant sources. See Appendix S.4.

L. Emergency Procedures.

Describe the emergency instructions to be posted in all laboratory areas where radioactive materials are used.

A set of emergency procedures acceptable for most programs is contained in Appendix H.

M. Area Survey Procedures.

Describe the routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable, and provisions for maintaining records of surveys.

If the application is to cover multiple users and areas of use, the individual user should perform surveys of his own work areas in addition to those performed by the radiation safety staff. Acceptable procedures and frequencies for routine surveys are described in Appendix I.

N. Waste Disposal.

Describe specific methods used for disposal of radioactive waste. A licensee may dispose of waste by:

1. Segregation of non-radioactive waste from radioactive waste, decay of radioactive waste in storage until radiation levels have reached background levels, monitoring, and, decay of radioactive release to normal trash.

2. Release into a sanitary sewer in conformance with 902 KAR 100:021, Section 3.

3. Release into the air in conformance with 902 KAR 100:019, Section 44.

4. Alternative disposal methods specifically approved by the Cabinet.

5. Transfer to a person or firm properly licensed to receive such waste, (e.g., commercial waste disposal firms).

Complete the form contained in Appendix J to indicate waste disposal methods.

O. Therapeutic Use of Radiopharmaceuticals.

Describe special precautions for patients treated with radiopharmaceuticals in therapeutic doses. Although some procedures may be performed on an outpatient basis, appropriate procedures should be established because hospitalization is sometimes required.

1. Describe radiation safety procedures directly involved with care of therapy patients, including:

   (a) Procedures for assigning patients to rooms. Private rooms should be designated for I-131 therapy patients or any other patients that may constitute an internal or external exposure hazard for roommates.

   (b) Procedures for contamination control in the patient's room (e.g., protective covering for areas of likely contact, use of disposable dishes and utensils, and procedures for posting and controlling radiation areas or potentially contaminated areas).

   (c) Procedures for surveys of:

      (1) Areas, equipment, personnel involved in administration of radiopharmaceuticals,

      (2) The patient's room on a daily basis,

      (3) Unrestricted areas (i.e., areas adjacent to the patient's room),

      (4) Linens and other items removed from the patient's room, and

      (5) The patient's room before it is reassigned to another patient.

   (d) Records of surveys to be recorded on patient's chart and in radiation safety office records.

   (e) Instructions to nursing staff (see Exhibit 6).

   (f) Personnel monitoring procedures for medical and nursing staff.

   (g) Procedures for disposal of wastes, including:

      (1) Patient excreta,
      (2) Surgical dressings, and
      (3) Other disposable items.

(h) Procedures to be followed in case of emergency surgery or death (see NCRP Report Nos. 37 and 48).

(i) Procedures for release of patients, including:

(1) Criteria for release of patients and

(2) Instructions to patients and families.

2. Describe radiation safety procedures involved with all other aspects of therapy procedures, including:

(a) Criteria for determining when it is appropriate to use protective facilities, equipment, or supplies (e.g., hoods, shielding blocks, tongs, disposable gloves) and procedures for their use. Personnel should always wear gloves and work within fume hoods or special enclosures whenever opening vials containing therapeutic quantities of volatile radiopharmaceuticals such as I-131. These hoods should have adequate airflow, and operating procedures should be designed to prevent contamination of personnel and surrounding areas.

(b) Criteria and procedures for bioassay of personnel. Bioassays should also be considered for personnel (e.g., radiation safety, nursing) who are involved in aspects of therapy procedures. Significant thyroid uptakes have been detected in individuals who open and prepare oral solutions of I-131 for therapeutic doses. The licensee should measure the thyroid burden of each individual who helped prepare or administer a therapeutic dosage of iodine-131 within three days after administering the dosage. If the burden exceeds 0.04 microcuries of iodine-13l, an investigation for the cause and corrective action must be implemented.

(c) Surveys to limit the spread of contamination and procedures for decontamination. Surveys (e.g., measurement of I-131 in air; measurement of I-131 in the thyroid glands of laboratory personnel; contamination surveys of personnel, equipment, and facilities) should also be performed to determine compliance with 902 KAR 100:073, Section 37.

Submit detailed responses to Items O.1. and O.2. described above. In lieu of submitting a detailed response to Item O.1., you may state that you will follow the procedures in Appendix K.

P. Therapeutic Use of Sealed Sources.

Describe special procedures for patients treated with sealed sources. These procedures should include descriptions of:

1. The areas where sealed sources will be stored, including (1) placement and thickness of shielding, (2) proximity of the storage area to unrestricted areas, and (3) any calculations or measurement data used to check the adequacy of the shielding and other facility protection specifications. Radiation levels in unrestricted areas must be less than 2 millirems in any 1 hour. (902 KAR 100:019, Section 10)

2. Special precautions to be used while handling sealed sources.

3. Your method for determining the radiation doses to the extremities of personnel handling sealed sources.

4. The equipment and shielding available for transporting sources from storage sites to the place of use.

5. Your method for maintaining source accountability at all times. This should include a description of sign-in and sign-out procedures, periodic inventory, and the method for determining that all sources are accounted for and returned to storage immediately following the conclusion of treatment.

6. Surveys to be performed during the course of treatment and at the conclusion of treatment. The patient and room should be surveyed with a radiation survey instrument immediately following the conclusion of treatment and before the patient is discharged. This survey should include a source count and should be adequate to determine that all temporary implant sources have been removed from the patient and from all areas that the patient occupied.

7. Special instructions for nursing care of patients who are treated with sealed sources. (Appendix L to this guide contains a description of procedures to be followed for patients treated with sealed sources.)

Q. Air Concentration Control

1. Submit your procedure for estimating worker dose from submersion in noble gases. See Appendix M.

2. Submit your procedure for estimating worker dose from aerosol concentrations. See Appendix M.

3. Submit your procedure for estimating aerosol and gas concentration in effluents. See Appendix M.

4. Submit your procedure for calculating spilled gas clearance times. See Appendix M.

R. Procedures and Precautions for Use of Radioactive Material Specified in Item 7.

Clearly state any additional radiation safety procedures to be followed while individuals are using the material listed in Item 7 (e.g., air sampling, other special surveys, bioassays, leak testing sealed sources, including radiation safety precautions).

Bioassays may be required when individuals work with millicurie quantities of H-3, I-125, or I-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassays may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it likely that the radioactive material will be ingested, inhaled, or absorbed into the body. Show in the application that the need for bioassays has been thoroughly considered and that the proposed bioassay program is appropriate for the intended use of radioactive material.

S. Sealed Source Inventory

Describe the sealed source inventory program. All sealed sources received pursuant to the license shall be inventoried at intervals not to exceed three months (refer to 902 KAR 100:073, Section 19). The physical inventory shall include calibration/reference sources and brachytherapy sources, if authorized by the license. A written record of the inventory shall be maintained and shall include the quantities and kinds of radioactive material, distinctive individual sealed source identity such as model and serial number, location of sources, the date of the inventory and the signature of the radiation safety officer.

T. For Private Practice Applicants

Specific licenses for physicians in private practice are generally limited to physicians who are located in private offices and not on hospital premises. A Radiation Safety Committee is not required. Methods of use that require hospitalization of the patient are not permitted.

U. For Mobile Nuclear Medicine Service. See Appendix T.

V. Procedures for Reporting Misadministrations

Procedures must be commensurate with those in 902 KAR 100:073, Section 12. Exhibit 10 is a misadministration report form to be used in reporting any misadministrations.

Item 13 - Training and Experience of Users: Describe the training and experience with regards to radiation protection of authorized users and the Radiation Protection Officer.

A. Authorized User(s). If the physician has been previously authorized to use the radioactive material listed in this application, submit a copy of the license on which the individual is listed as a user.

   If the physician has not been previously authorized to use the radioactive material listed, state where he is licensed to practice medicine and submit a complete description of his training and experience on Form RPS-8, Training and Experience/Preceptor Statement form (Exhibit 2). Criteria for acceptable training and experience are contained in Appendix A of this guide.

B. Radiation Safety Officer. If the radiation safety officer is not one of the physicians named in Item 5, submit a complete description of his training and experience. When a consultant is employed to assist the radiation safety officer, the institution will be responsible for the proper performance of the radiation safety program as required by the license and the institution's radiation safety officer will be expected to review the consultant's work and sign the required reports and records. Refer to 902 KAR 100:073, Sections 47 and 48 for training requirements.

Item 14 - Waste Disposal: This item was discussed in Item 12 paragraph N. of this guide.

VI. AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make any

changes in the facilities, equipment (including types of monitoring and survey instruments), procedures, authorized users or radiation safety officer, or radioactive material to be used.

Applications for license amendments may be filed either on the application form or in letter form. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph.

Amendment applications should be signed and dated by a representative of the licensee's administrative management (e.g., the hospital administrator). An original and one copy of the application for amendment should be prepared. The original should be submitted, as in the cases for new or renewal applications, and a copy maintained by the licensee.

VII. RENEWAL OF A LICENSE

Radioactive material licenses are renewed annually by payment of a renewal fee. The renewal fee must be received by the Radiation Health & Toxic Agents Branch thirty (30) days prior to the expiration date of the license.

APPENDIX A

ACCEPTABLE TRAINING AND EXPERIENCE FOR
MEDICAL USES OF RADIOACTIVE MATERIAL
(902 KAR 100:073, Sections 47 – 59)

General Criteria

Any human use of radioactive material (i.e., the internal or external administration of radioactive material, or the radiation therefrom, to human beings) must be carried out by or under the supervision of a physician.

902 KAR 100:073 provides that the Cabinet will approve a license application for medical use of radioactive material if it determines, among other things, that the physician designated as the individual user is adequately trained and experienced in (a) basic radioisotope handling techniques and (b) the clinical management of patients to whom radiopharmaceuticals have been administered. Outlined below are training and experience criteria that the Cabinet has found acceptable for physicians who use radiopharmaceuticals.

This training and experience must have been obtained within a 7-year period proceeding the date of the license application or must be supplemented by continuing education or experience. Also, the original training and experience should have been received in a formal residency program in an accredited medical institution. Each physician's training and experience is examined on a case-by-case basis.

A. Training for Routine Diagnostic Procedures (902 KAR 100:073, Sections 49 and 50)

To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Sections 29 and 31 in 902 KAR 100:073, a physician should have the following number of hours (hours are in terms of class, laboratory, or clinical experience rather than semester hours) in the topics listed.

1. <u>Imaging and Localization Studies</u>

(a) Training in basic radioisotope handling techniques applicable to the use of unsealed sources. This training should consist of laboratory and classroom instruction in the following areas: (200 hours)

(1) Radiation physics and instrumentation (100 hours)

(2) Radiation protection (30 hours)

(3) Mathematics pertaining to the use and measurement of radioactivity (20 hours)

(4) Radiation biology (20 hours)

(5) Radiopharmaceutical chemistry (30 hours)

(The hours listed next to each of the five subjects above are suggested values and should not be interpreted as specific requirements.)

(b) Supervised experience with the types and quantities of radioactive material for which the application is being made, or equivalent (500 hours). The experience under the supervision of an authorized user should include experience in:

(1) Ordering, receiving and unpacking radioactive materials.

(2) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters.

(3) Calculating and safely preparing patient dosages.

(4) Using administrative controls to prevent misadministration of radioactive material.

(5) Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures.

(6) Eluting technetium-99m from generator systems, assaying and testing the elute for molybdenum-99 and alumina contamination, and processing the elute with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(c) Supervised clinical training in an institutional nuclear medicine program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include:

(1) Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.

(2) Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement, and plotting data.

(3) Follow up of patients when required.

(4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc. or see ‘Note A.’

2. Uptake, Dilution and Excretion Studies

(a) Training in basic handling techniques (40 hrs) applicable to the use of unsealed sources. This training should consist of laboratory and classroom instruction in the same topics described in Section A.1.(a) of this appendix.

(b) Supervised clinical training in an institutional nuclear medicine program (20 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include training as outlined below (902 KAR 100:073, Section 49):

(1) Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications.

(2) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages.

(3) Administering dosages to patients and using syringe radiation shields.

(4) Collaborating with the authorized user in the interpretation of radionuclide test results; and

(5) Patient follow up; or see 'Note A.'

NOTE A:

The requirements specified in Sections A.l. and A.2., may be satisfied concurrently in a 6 month training program IF all three areas are integrated into the program, as specified in 902 KAR 100:073, Sections 49 and 50.

NOTE B:

For each physician named in Item 5 of Form RPS-7, complete Form RPS-8, Training and Experience/Preceptor Statement. For each subject covered in basic training, state where the training was obtained, the dates, total number of hours, and type of training. Hours of training should be broken down into lecture or laboratory hours or on-the-job training (OJT). OJT must have been obtained in a formalized training program. Be sure that individual hours of training can be traced to the institution where the training was received. Each hour of training should be listed under only one subject category (i.e., the most applicable subject category).

ALTERNATIVES

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:

1. Verification of certification in nuclear medicine by the American Board of Nuclear Medicine,

2. Verification of certification by the American Board of Radiology in Diagnostic Radiology, verification of certification in diagnostic radiology or radiology by the American Osteopathic Board of Radiology, or verification of certification in nuclear medicine by the American Osteopathic Board of Nuclear Medicine, or verification of certification in nuclear medicine by the Royal College of Physicians and Surgeons of Canada,

3. A copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

B. Training for Specific Diagnostic Procedures

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of radioactive material being requested. Such requests will be examined on a case-by-case basis by the Cabinet.

C. Training for Therapy Procedures Involving Radiopharmaceuticals (902 KAR 100:073 Section 51)

To qualify as adequately trained to use or directly supervise the use of radioactive material as a radiopharmaceutical for certain therapeutical uses, a physician should have:

1. Training in basic radioisotope handling techniques applicable to the use of unsealed sources for therapy procedures including: (80 hours)

   (a) Radiation physics and instrumentation (25 hours)

   (b) Radiation protection (2 hours)

   (c) Mathematics pertaining to the use and measurement of radioactivity (10 hours)

   (d) Radiation biology (20 hours)

   (These requirements are in lieu of, not in addition to, those Section A.l.(a) above.)

2. Clinical training under the supervision of an authorized user at a medical institution in the following:

   (a) 1-131 for treatment of hyperthyroidism and/or cardiac conditions:

   Clinical experience in the diagnosis of thyroid function and active participation in the treatment of ten (10) patients.

   (b) Soluble P-32 for treatment of ascites, polycythemia vera, leukemia, and/or bone metastases:

   Active participation in the treatment of three (3) patients with any combination of these three conditions.

   (c) I-131 for treatment of thyroid carcinoma:

   Clinical experience in the treatment of three (3) patients with thyroid carcinoma.

(d) Colloidal chromic P-32 or colloidal Au-198 for intracavitary treatment of malignant effusions:
Active participation in the treatment of three (3) patients.

(e) Sr-89 or Sm-153 as chlorides for the treatment of pain associated with bone metastases:
Active participation in the treatment of three (3) patients.

ALTERNATIVES

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:

1. Verification of certification in nuclear medicine by the American Board of Nuclear Medicine,

2. Verification of certification by the American Board of Radiology in radiology, therapeutic radiology or radiation oncology, or verification of certification in nuclear medicine or radiation oncology by the American Osteopathic Board of Radiology after 1984, or verification of certification in nuclear medicine by the Royal College of Physicians and Surgeons of Canada, or

3. A copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

D. Training for Therapy Procedures Involving Sealed Sources (902 KAR 100:073, Section 52)

To qualify as adequately trained to use or directly supervise the use of sources and devices containing radioactive material for certain medical uses, a physician should have:

1. Training in basic radioisotope handling techniques applicable to the use of unsealed sources for therapy procedures, consisting of lectures, laboratory sessions, discussion groups, or supervised experience in the following areas: (200 hours)

(a) Radiation physics and instrumentation (110 hours)

(b) Radiation protection (40 hours)

(c) Mathematics pertaining to the use and measurement of radioactivity (25 hours)

(d) Radiation biology (25 hours

(The hours listed next to each of the four subjects above are suggested values and should not be interpreted as specific requirements.)

2. Experience with the types and quantities of radioactive material for which the application is made, or equivalent (500 hours). Training under the supervision of an authorized user should include training in:

   (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

   (b) Checking survey meters for proper operation;

   (c) Preparing, implanting, and removing sealed sources;

   (d) Using administrative controls to prevent the misadministration of radioactive material; and

   (e) Using emergency procedures to control radioactive material.

3. Clinical training in sealed source and device procedures:

   (a) To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

      (1) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

      (2) Selecting the proper brachytherapy sources, dose, and method of administration;

      (3) Calculating the dose: and

      (4) Postadministration follow up and review of case histories in collaboration with the authorized user.

NOTE:

Evidence of certification by the American Board of Radiology in Radiology, Therapeutic Radiology or Radiation Oncology, certification in radiology, with a specialization in radiotherapy as a British 'Fellow of the Faculty of Radiology' (FFR) or 'Fellow of the Royal College of Radiology' (FRCR), Radiation Oncology by the American Osteopathic Board of Radiology or Canadian certification from the Royal College of Physicians and Surgeons (RCPS) in Therapeutic Radiology may be submitted in lieu of the information requested in Sections 1 through 3 above. Evidence of previous approval by the NRC or an Agreement State may also be submitted in lieu of the information requested above. In this case, the applicant should submit a copy of the Agreement State license or NRC license on which the applicant-physician was specifically listed as an authorized user.

E. Training for Physicians Wishing to Use Sr-90 Ophthalmic Eye Applicators Only (902 KAR 100:073, Section 54)

To qualify as adequately trained to use or supervise the use of an Sr-90 eye applicator only, a physician should submit:

1. Evidence of certification by the American Board of Radiology in radiology, therapeutic radiology or radiation oncology, or

2. Evidence of:

(a) Active practice in therapeutic radiology or ophthalmology, -and

(b) Training in basic radioisotope handling techniques, including (24 hours)

(1) Radiation physics and instrumentation (6 hours)

(2) Radiation protection (6 hours)

(3) Mathematics pertaining to the use and measurement of radioactivity (4 hours)

(4) Radiation biology (8 hours)

(The hours listed next to each of the four subjects are suggested minimum values and should not be interpreted as specific requirements.)

(c) Evidence of active participation in the treatment of five patients.

"Active participation" should include supervised examination of patients, collaboration and calculations concerning the dose to be used, administration of the dose to the patient, and follow up and study of patient case histories.

F. Training for Physicians Wishing to Use Sealed Sources for Diagnosis (See 902 KAR 100:073, Section 55).

To qualify as adequately trained to use sealed sources for diagnosis, the user shall be a physician, dentist or podiatrist who:

1. Is certified in:

(a) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

(b) Nuclear medicine by the American Board of Nuclear Medicine; or

(c) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(d) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

2. Has completed eight (8) hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training shall include:

(a) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(b) Radiation biology; and

(c) Radiation protection and training in the use of the device for the purposes authorized by the license.

APPENDIX B

MODEL RADIATION SAFETY COMMITTEE CHARTER AND RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY (902 KAR 100:073, Sections 5, 6, & 7)

You may use the following text as it appears here, indicating on your application, 'We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix B to 'Medical Programs Licensing Guide Revised March 2000.'

If you prefer, you may develop your own statement of authority, duties, administrative procedures, and delegation of authority. If you do so, you should consider for inclusion all the features in the model text and carefully review the requirements of 902 KAR 100:073, Section 6.

MODEL CHARTER

Charge. The Committee shall:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;

2. Ensure that licensed material is used in compliance with Cabinet regulations and the institutional license;

3. Establish a table of investigational levels for individual occupational radiation exposures; and

4. Ensure that the use of licensed material is consistent with the ALARA philosophy and program; and

5. Identify program problems and solutions.

Responsibilities. The Committee shall:

1. Be familiar with all pertinent Cabinet regulations, the license application, the license, and amendments;

2. Review the training and experience of the proposed authorized users and the Radiation Safety Officer (RSO) to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;

3. Review on the basis of safety and approve or deny, consistent with the limitation of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution;

4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;

5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;

6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing security, housekeeping, physical plant) are appropriately instructed as required in 902 KAR 100:165.

7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with Cabinet regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of Cabinet inspections, written safety procedures, and the adequacy of the management control system;

8. Recommend remedial action to correct any deficiencies identified in the radiation safety program;

9. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and

10. Ensure that the byproduct material license is amended, if required, prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

1. The Committee shall meet as often as necessary to conduct its business but no less than once in each calendar quarter.

2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management is defined as the chief executive officer or that person's delegate or delegates who have authority to provide necessary resources to achieve regulatory compliance. Membership of the radiation safety committee is normally defined by position and not by name. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plant, housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.)

3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

MODEL DELEGATION OF AUTHORITY

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management of situations where staff are not cooperating and not addressing radiation safety issues. In addition, you are free to raise issues with the Radiation Health & Toxic Agents Branch, Cabinet for Health Services, Frankfort, KY at anytime.

_____
Signature of Management

I accept the above responsibilities.

_____
Signature of the Radiation Safety Officer

APPENDIX C

INSTRUMENTATION

A. Survey meters:

a. Manufacturer's name: _____

Manufacturer's model number: _____

Number of instruments available: _____

Minimum range: _____ mR/hr to _____ mR/hr

Maximum range: _____ mR/hr to _____ mR/hr

b. Manufacturer's name: _____

Manufacturer's model number: _____

Number of instruments available: _____

Minimum range: _____ mR/hr to _____ mR/hr

Maximum range: _____ mR/hr to _____ mR/hr

B. Dose calibrator:

Manufacturer's name:_____

Manufacturer's model number: _____

Number of instruments available: _____

C. Instruments used for diagnostic procedures:

Type of Instrument	Manufacturer's Name	Model No.

D. Other (e.g., liquid scintillation counter, area monitor, velometer) including instrumentation used for counting contamination swipes:

APPENDIX D

CALIBRATION OF INSTRUMENTS
PART A
(902 KAR 100:073, Section 16)

Check appropriate items.

____1. Survey instruments will be calibrated at least annually and following repair or maintenance that may affect the calibration of the instrument.

____2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ±10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated:

____ a. By the manufacturer.

____ b. At the licensee's facility.

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

____ (2) The step-by-step procedures, including radiation safety procedures, are attached.

____ c. By a consultant or outside firm

(1) Name _____
(2) Location _____

(3) Procedures and sources

____ have been approved by an Agreement State or the U.S. NRC. A copy of the license, the procedures, and a description of the sources are attached. The calibration report will contain the information on

— the attached "Certificate of Instrument Calibration."
— the consultant's reporting form as attached.

__ are described in the attachment, and the consultant's report will contain the information on

— the attached "Certificate of Instrument Calibration."
__ the consultant's reporting form as attached.

4. Daily constancy and battery checks of survey instruments used for radiation purposes shall be made.

5. Records demonstrating that the licensee has complied with the procedures indicated above in Items 1 through 3 shall be maintained for inspection by the Cabinet for Health Services.

CERTIFICATE OF INSTRUMENT CALIBRATION

For:

Instrument:

Manufacturer _____

Type _____

Model No. _____

Serial No. _____

Calibration Data:

Scale	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)

Comments:

Nuclide	Activity or Exposure Rate at Specified Distance	Calibration Accuracy

Calibration Source:

Calibrated by _____ Date _____

APPENDIX D
PART B

Check appropriate items.

____1. All radiopharmaceuticals will be assayed for activity to an accuracy of ± 10 percent of the true value prior to being administered to patients. Such assays shall be performed using the dose calibrator listed in response to item 8 of this application.

____2. The dose calibrator shall be checked for accurate operation using the dose calibrator quality assurance procedures contained in Appendix D, Part B of the Kentucky Cabinet for Health Services Guide for the Preparation of Radioactive Material License Applications for Medical Programs (as revised March 2000). Such procedures shall be performed at intervals not exceeding those listed in Appendix D, Part B.

____3. Complete the table below listing sealed sources used for dose calibrator quality assurance.

Instrument Constancy

Manufacture	Model	Nuclide	Activity (mCi)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Instrument Accuracy*

_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

* Sources used for instrument accuracy shall have been calibrated by comparisons with standard sources that have been assayed by NBS. State in activity (above) the calibration accuracy. Documentation of this source calibration shall be maintained by the licensee.

____4. Quality control and maintenance of instrumentation used for diagnostic procedures shall be performed routinely in accordance with the manufacturer's recommendations. (Attach a copy of such procedures.)

____5. Records demonstrating the licensee has complied with the procedures indicated in Items 1 - 4 shall be maintained for inspection by the Cabinet for Health Services.

QUALITY ASSURANCE PROCEDURES FOR DOSE CALIBRATOR
(902 KAR 100:073, Section 15)

Test for the following:

1. Instrument constancy (at installation and daily thereafter).

2. Instrument accuracy (at installation and at intervals not to exceed 12 months thereafter).

3. Instrument linearity (at installation and at intervals not to exceed 3 months thereafter).

4. Geometrical variation (at installation).

5. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

After repair, adjustment, or relocation of the dose calibrator, repeat all the appropriate tests.

Test for Instrument Constancy

Assay one relatively long-lived reference source, such as Cs-137 or Co-57, using a reproducible geometry before each day's use of the instrument. The source shall have an activity of at least 50 microcuries of a photon-emitting radionuclide with a half-life greater than 90 days.

1. Assay the source using a frequently used setting (i.e., Cs-137 setting for Cs-137).

2. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.

3. Calculate net activity of each source subtracting out background level.

4. For each source, plot net activity versus the day of the year on semi-log paper.

5. Log the background levels.

6. Indicate the predicted activity of each source based on decay calculations and the ± percent limits on the graph.

7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.

8. Variations greater than ± 10 percent from the predicted activity indicate the need for instrument repair or adjustment.

9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

Test of Instrument Linearity

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

1. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time, for example, 8 a.m.

2. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 30 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

3. Convert the time and date information you recorded to hours elapsed since the first assay.

4. On a sheet of semi-log graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.

5. Draw a 'best fit' straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A=observed – A-line)/(A-line) = deviation.

6. If the worst deviation is more than ± 10 percent, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

7. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them.

1. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps 2 through 4 below must be completed within 6 minutes.

2. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

3. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

4. Continue for all sleeves.

5. Complete the decay method linearity test steps 2 through 7 above.

6. From the graph made in step 4 of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step 2.

7. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step 2.

8. Continue for all sleeves.

9. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

1. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

2. Steps 3 through 5 below must be completed within 6 minutes.

3. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

4. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

5. Continue for all sleeves.

6. On a sheet of semi-log graph paper label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.

1. Plot the data using the equivalent decay time associated with each sleeve.

8. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A=observed – A-line)/A-line = deviation.

9. If the worst deviation is more than ± 10 percent, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

10. Put a sticker on the dose calibrator that says when the next linearity test is due.

Test for Geometrical Dependence

Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for

injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3 cc plastic syringes and that radiopharmaceutical kits are made in 30 cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

1. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.

2. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated.

3. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

4. Repeat the process until you have assayed a 2.0-cc volume.

5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

6. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

7. To test the geometry dependence for a 30 cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

8. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

9. Repeat the process until you have assayed a 19 cc volume. The entire process must be completed within 10 minutes.

10. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

11. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

Test for Instrument Accuracy

Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. The regulations also require that sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

1. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.

2. Repeat step 1 for a total of 3 determinations, and average results.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within ± 5 percent after decay corrections.

4. Repeat the above steps for the commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks that do not agree within ± 10 percent indicate that the instrument must be repaired or adjusted.

7. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. Keep a log of these initial and subsequent readings.

APPENDIX E

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL (902 KAR 100:019 and 040)

1. The Supervisory Nuclear Medicine Technologist or chief nuclear medicine physician will place all orders for radioactive material and will ensure that the requested material and quantities are authorized by the license and that possession limits are not exceeded.

2. A system for ordering and receiving radioactive material will be established and maintained. The system will consist minimally of the following:

    a. Ordering of routinely used material

        (1) Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.

        (2) The written records will be referenced when opening or storing radioactive shipment.

    b. Ordering of specially used material (e.g., therapeutic uses):

        (1) A written request will be obtained from the physician who will perform the procedure.

        (2) Persons ordering the material will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.

        (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.

    c. It is essential that written records be maintained for all ordering and receipt procedures.

3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

4. During off-duty hours, security personnel or other designated individuals will accept delivery of radioactive packages in accordance with the written procedures for ordering and receiving radioactive material.

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL (902 KAR 100:019, Section 28)

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the quantity limits as specified in 902 KAR 100:019, Section 28. They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of 902 KAR 100:019, Section 28. All shipments of liquids greater than exempt quantities will be tested for leakage. The Cabinet will be notified in accordance with the regulations if removable contamination exceeds 0.001 microcurie (2,200dpm)/l00 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1m).

2. For all packages, the following additional procedures for opening packages will be carried out:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

   c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface; the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5millirem per hour at the package surface. (See 172.403 of 49 CFR Part 172.)

   d. Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.
      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip, and label on bottle. [In the case of special orders (e.g., therapy doses), also compare with physician's written request.]
      (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
      (4) Check also that shipment does not exceed possession limits.

   e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity (e.g. dpm/100 cm^2 etc.). The licensee should specify in the procedure manual which instrument (for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter) should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement. Take precautions against the potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.

g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding in regular trash.

h. Make a record of the receipt.

3. For packages received under the general license in 902 KAR 100:050 the following procedure for opening each package will be followed:

a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.

b. Check to ensure that the material received is the material that was ordered. See Exhibit 5 for a sample record form you may want to use.

APPENDIX G

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposal gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 percent.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals. Ring badges should be worn toward the palm side of the hand for measuring hand exposure.

9. Dispose of radioactive waste only in specially designated and properly shielded receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate in accordance with survey procedures.

12. Confine radioactive solutions in covered containers that are plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

14. Sources with even a small amounts of radioactivity can exhibit a high dose rate on contact, therefore you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

15. Use remote handling devices (tongs) when working with radioactive material.

APPENDIX H

EMERGENCY PROCEDURES

You may use the following model spill procedures as they appear here, indicating on your application, "We will establish and implement the model spill procedures published in Appendix H to Medical Program Licensing Guide, Revised March 2000."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures.

MODEL PROCEDURES

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.

2. Prevent the spread of contamination by covering the spill with absorbent paper.

3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.

4. Survey the area with a low-range radiation detector survey meter. Check the area around the spill. Also check your hands, clothing and shoes for contamination.

5. Report incident to the Radiation Safety Officer (RSO).

6. The RSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 3) and the Radioactive Spill Contamination Survey (see Exhibit 4).

Major Spills of Liquids and Solids

1. Clear the area. Notify persons not involved in the spill to vacate the room.

2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

3. Shield the source if possible, but only if it can be done without further contamination or a significant increase in radiation exposure.

4. Close the room and lock or otherwise secure the area to prevent entry.

5. Notify the Radiation Safety Officer immediately.

RADIATION SAFETY OFFICER: _____
OFFICE PHONE: _____
HOME PHONE: _____

ALTERNATIVE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER: _____

_____

_____

6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

7. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 3) and the Radioactive Spill Contamination Survey (see Exhibit 4).

The following is not part of the model spill procedure:

Major Spills and Minor Spills

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill procedure may be restricted access pending compete decay.

Table 1, which may be used as general guidance to determine whether a major spill procedure for a minor spill procedure should be implemented, was developed based on a comparison of information from the following sources:

1. "Standards for Protection Against Radiation," Proposed Rule, Part 20, published January 9, 1986, Appendix B, Table 1, Column 3 (Derived Air Concentration Values)., 51 FR 1092.

2. "Gamma Radiation Levels for One Curie of Some Radionuclides,". Radiological Health Handbook, January 1970 edition, Department of Health, Education, and Welfare, Washington, DC, p. 131.

3. National Council on Radiation Protection and Measurements, "Safe Handling of Radioactive Materials," NCRP Report No. 30, Paragraph 2.3 and Table 2, 1964.

4. "Upgraded Emergency Preparedness for Certain Fuel Cycle and Materials Licensees," Advance Notice of Proposed Rulemaking on Parts 30, 40 and 70, 46 FR 29712, Table 1, June 3, 1981.

Table 1 may need to be modified before being used for guidance in a specific area of use.

TABLE H-1

Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	10	Tc-99m	100
Cr-51	100	In-111	10
Co-57	100	I-123	10
Co58	10	I-125	1
Fe-59	10	I-131	1
Co-60	1	Yb-169	10
Ga-67	100	Hg-197	100
Se-75	10	Au-198	10
Sr-85	10	Tl-201	100

Spill Kit

You may also want to consider assembling a spill kit that contains:.

6 pairs disposable gloves, 1 pair housekeeping gloves
2 disposable lab coats
2 paper hats
2 pairs shoe covers
1 roll absorbent paper with plastic backing
6 plastic trash bags with twist ties
“Radioactive Material” labeling tape
1 china pencil or marking pen
3 prestrung “Radioactive Material” labeling tags
Supplies for 10 contamination wipe samples
Instructions for “Emergency Procedures”
Clipboard with one copy of Radioactive Spill Report Form
Pencil

Forms

You may want to use Exhibit 3, Radioactive Spill Report, and Exhibit 4, Radioactive Spill Contamination Survey Forms.

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

If personnel involved in the surgical procedure are likely to receive exposures exceeding the non-occupational permissible dose limits specified in 902 KAR 100:019, Section 10, the following procedures will be followed:

1. If emergency surgery is performed within the first 24 hours following the administration of I-31 sodium iodine, fluids (e.g., blood, urine, etc.,) will be carefully removed and contained in a closed system.

2. The surgeon and the personnel involved in the surgical procedures will wear protective gear for the protection of the eyes from splashing of foreign materials, as well as from beta radiation.

3. The RSO will direct personnel in methods to keep doses ALARA during surgical procedures.

4. If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced in the wound. The RSO will be informed of any possible radiation hazard.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

If personnel involved in the autopsy are likely to receive exposures exceeding the non-occupational permissible dose limits specified in 902 KAR 100:019, Section 10, the following procedures will be followed:

1. Upon the death of the therapy patient, the authorized user in charge and the RSO will be notified immediately.

2. An autopsy will be performed only after consultation and permission from the RSO.

3. Protective eyewear will be worn by the pathologist and his assistants for protection from possible splashing of foreign materials and exposure from beta radiation.

4. If an entire block of tissue containing the radionuclide can be removed during autopsy, this will be done first. The remainder of the autopsy can then proceed as usual.

5. The RSO will evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.

6. When possible, separate organs will be promptly removed from the body, and detailed dissection will be carried out a safe distance away from the body.

7. After selected small samples have been removed, the radioactive tissues that are retained will promptly be placed in appropriately shielded vessels for storage or disposed according to procedures deemed appropriate by the RSO and in accordance with the regulations.

8. If an injury occurs during the autopsy which results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced in the wound. The RSO will be informed of any possible radiation hazard.

APPENDIX I

AREA SURVEY PROCEDURES
(902 KAR 100:073, Section 24)

1. All areas where radiopharmaceuticals are routinely prepared for use or administered will be surveyed daily with an appropriately low-range survey meter and decontaminated if necessary.

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 microcuries) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. Surveys for removable contamination shall be conducted weekly for areas where radiopharmaceuticals are prepared and administered and for storage areas.

5. The daily and weekly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 2000 dpm per 100 cm^2 for the contaminant involved (200 dpm/l00 cm^2 for isotopes of iodine in an unrestricted area).

6. A permanent record will be kept of all survey results, including negative results. The record will include:

   a. Location, date, and identification of equipment used, including the model and serial numbers, and pertinent counting efficiencies.

   b. Name of person conducting the survey and established action levels for each area.

   c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   e. Detected contamination levels, keyed to locations on drawing.

   f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

7. Area will be cleaned if the contamination level exceeds 2000 dpm/100 cm^2 (200 dpm/l00 cm^2 for iodine in an unrestricted area).

APPENDIX J

WASTE DISPOSAL

1. Liquid waste will be disposed of (check as appropriate)

____ In the sanitary sewer system in accordance with 902 KAR 100:021, Section 3.
____ By commercial waste disposal service (see also Item 4 below).
____ Other (specify): _____

2. Mo-99/Tc-99m generators will be (check as appropriate)

____ Returned to the manufacturer for disposal.

____ Held for decay for ten (10) half lives and radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. Be sure that waste storage areas were described in your application and that they are surveyed periodically. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash. These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

____ Disposed of by commercial waste disposal service (see Item 4).
____ Other (specify): _____

3. Other solid waste will be (check as appropriate)

___ Held for decay for ten (10) half lives and radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

____ Disposed of by commercial waste disposal service (see Item 4).
____ Other (specify): _____

4. The commercial waste disposal service used will be

_____
(Name) (City, State)

NRC/Agreement State License No. _____

5. For each waste disposal method indicated above, submit a step-by-step procedure instructing employees in the disposal method. Such procedures should describe the controls used to ensure regulatory limits are not exceeded. Refer to 902 KAR 100:021, Section 3 (sanitary sewer releases) and 902 KAR 100:019 (airborne releases and effluent releases) if necessary.

APPENDIX K

MODEL PROCEDURES FOR RADIATION SAFETY FOR USE 0F RADIOPHARMACEUTICALS IN THERAPY
(902 KAR 100:073, Sections 25, 36 and 37)

You may use the following procedure for reducing worker and public dose during radiopharmaceutical therapy. If you will follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix K to Medical Programs Licensing Guide, Revised March 2000."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 902 KAR 100:073, Sections 25, 36, and 37.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.

2. Prepare the room for the procedure as follows:

    a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, doorknobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.

    b. Prepare separate boxes for linen, disposable waste, and non-disposable contaminated items. Place a single large resealable plastic bag in each box, or supply several small plastic bags.

    c. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.

        (1) Containers should be unbreakable and resealable.

        (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.

        (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper.

        (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm of lead.)

        (5) Supply a wide-mouth anti-splash funnel.

d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

4. Supply the nurses with film badges or TLDs.

5. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Iodine-l31, Phosphorus-32, or Gold-198' (Exhibit 6), or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

6. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

7. Only those persons needed for medical, safety, or training purposes should be present during the administration.

8. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in 902 KAR 100:019, Section 10). Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter sign out form. Post the room with a "Radioactive Materials" sign.

10. For patients treated with liquid or gelatin-capsuled I-131, within 3 days after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also, consider a thyroid burden assay for patient care personnel after the administration. Make a record of the worker's name, amount of I-31 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.

11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.

12. Do not release any patient until either the exposure rate from the patient is less than 7 millirem per hour at 1 meter or the retained radioactivity is less than 33 millicuries. If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.

    a. Remove all absorbent paper, and place it in the appropriate container.

    b. Transfer all containers to a decay-in-storage or decontamination area.

    c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm^2.

d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

Exhibit 7,“Radiation Safety Checklist for Iodine Therapy over 33 Millicuries,” may also be helpful to you.

APPENDIX L

MODEL PROCEDURE FOR THERAPEUTIC USE OF SEALED SOURCES
(902 KAR 100:073, Sections 25, 42, 43 and 44)

You may use the following procedure to reduce worker and public dose during implant therapy. If you will follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for radiation safety during implant therapy that was published in Appendix L to "Medical Programs Licensing Guide, Revised March 2000."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 902 KAR 100:019, Section 10, and 100:073, Sections 25, 42, 43 and 44.

You may find a checklist to be helpful, such as Exhibit 8, "Radiation Safety Checklist for Temporary Implant Therapy."

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room unless the dose at one meter from the implant meets the requirements in 902 KAR 100:019, Section 10.

2. Supply the nurses with film badges or TLDs.

3. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Temporary Implant Sources," Exhibit 9, or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing.

4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable consistent with good medical care.

5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.

6. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

7. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in 902 KAR 100:019, Section 10. Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter sign out form. Post the room with a "Radioactive Materials" sign.

8. Do not release any patient who has received a temporary implant from the hospital until both a radiation survey of the patient and a count of implant sources, trains, or ribbons confirms that all sources have been removed from the patient and are accounted for. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source running inventory form. For low-activity seeds (less than 1 millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.

9. Do not release any patient who has received a permanent implant from the hospital until the exposure rate from the patient is less than 7 mR/hr at 1 meter. Measure this exposure rate with a radiation measurement survey meter at a distance of 1 meter from the umbilicus with the patient standing.

You may want to use the sample forms in Exhibit 8, "Radiation Safety Checklist for Temporary Implant Therapy," and Exhibit 9, "Nursing instructions for Patients Treated with Temporary Implant Sources."

APPENDIX M

MODEL PROCEDURE FOR MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS
(902 KAR 100:019, Section 44 and 100:073, Sections 27 & 33)

WORKER DOSE FROM NOBLE GASES (Item M.l)

Noble gases such as xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.

If you will collect spent gas in a shielded trap with an effluent air contamination monitor and will follow the monitor manufacturer's instructions for checking its accuracy and constancy, you may respond to Item M.l by saying, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you will collect spent gas in a shielded trap and will follow the model procedure for checking trap effluent, you may respond to Item M.l by saying, "We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix M to "Medical Programs Licensing Guide, Revised March 2000."

If you are not monitoring trap effluent or if you exhaust spent gas to the atmosphere, you must estimate worker dose by calculation. If you will follow the model procedure below for calculating worker dose from noble gases, you may respond to Item M.l by saying, "We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix M to "Medical Programs licensing Guide, Revised March 2000."

If none of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of 902 KAR 100:019, Sections 44 and 100:073, Sections 27 and 33.

WORKER DOSE FROM AEROSOLS (Item M.2)

If you will collect spent aerosol in a shielded trap, will use an air contamination monitor for reusable traps, and will follow the manufacturer's instructions for checking for accuracy and constancy, you may respond to Item M.2 by saying, "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions." You do not have to monitor the trap effluent of single-use devices.

If you are not monitoring reusable trap effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation. If you will follow the model procedure below for calculating worker dose from aerosols, you may respond to Item M.2 by saying, "We will follow the model procedure for calculating worker dose from aerosols that was published in Appendix M to "Medical Programs Licensing Guide, Revised March 2000."

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of 902 KAR 100:019, Sections 44 and 100:073, Sections 27 and 33.

M.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS

1. Collect the following data:

   a. Estimated number of studies per week;

   b. Activity to be administered per study;

   c. Estimated activity lost to the work areas per study (you may assume 20 percent loss);

   d. Measured airflow supplied by each vent in the imaging room (if different during heating and cooling seasons, use the lesser value);

   e. Measured airflow exhausted by each vent in the imaging room (the exhaust should be vented and not recirculated within the facility);

   f. Measured airflow exhaust at the storage site (e.g., a fume hood); and

   g. Maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-4} uCi/ml in restricted areas and 5×10^{-7} uCi/ml in unrestricted areas. For soluble Tc-99m, the maximum permissible values are 7×10^{-5} uCi/ml in restricted areas and 2×10^{-7} uCi/ml in unrestricted areas. For other gases or aerosols, see 902 KAR 100:019, Section 44.

2. The following calculations must be made:

   a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.

   b. The estimated average concentration in restricted areas.

      (1) The total activity released to the restricted area (activity used each week multiplied by estimated fractional loss per study) divided by the total air exhausted (sum of all exhaust rates multiplied by the length of the work week) must be less than the applicable maximum permissible value for a restricted area.

      (2) If this is not the case, plan for fewer studies. (An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.)

M.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

1. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable maximum permissible value for an unrestricted area.

2. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

M.3 MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions and keep a record of the checks.

2. If you do not monitor the trap effluent, check it on receipt and once each month. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas, and compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.

3. The RSO will establish an action level based on cpm or a multiple of background cpm. If you measure a significant increase in the bag cpm, the trap is breaking down and must be replaced.

4. Follow the trap manufacturer's instructions for replacing the trap.

PUBLIC DOSE FROM AIRBORNE EFFLUENT (Item M.3)

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value in 902 KAR 100:019, Section 44.

If you are not directly venting aerosols and gases to the atmosphere, you may respond to Item M.3 by saying, "We will not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary.'

If you are going to vent aerosols or gases to the atmosphere, you must estimate effluent concentrations by calculation. If you will follow the model procedure below for calculating release concentrations, you may respond to Item M.3 by saying, 'We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix M to "Medical Programs Licensing Guide, Revised March 2000."

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of 902 KAR 100:019, Sections 44 and 100:073, Sections 27 and 33.

SPILL GAS CLEARANCE TIME (Item M.4)

Because normal room ventilation is usually not sufficient to ensure timely clearance of-spilled gas, the calculations described in Appendix M.4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

If you will calculate spilled gas clearance times according to the following procedure, you may respond to Item M.4 by saying, 'We will calculate spilled gas clearance times according to the procedure that was published in Appendix M.4 to 'Medical Programs Licensing Guide, Revised March 2000."

You may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of 902 KAR 100:073, Section 33.

M.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

1. Collect the following data:

a. A, the highest activity of gas in a single container, in microcuries;

b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value), in milliliters per minute;

c. Q, the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially installed gas exhaust system;

d. C, the maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-4} uCi/ml in restricted areas and 5×10^{-7} uCi/mil in unrestricted areas. For other gases, see 902 KAR 100:019.

e. V, the volume of the room in milliliters.

2. For each room make the following calculations:

a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.

b. The evacuation time $t = \frac{-V}{Q} \times \ln (C \times V/A)$.

APPENDIX N

PERSONNEL TRAINING PROGRAM

All personnel working with, or in the vicinity of radioactive material will receive proper instruction, appropriate to their activities. Personnel include radiation workers, clerical, nursing, housekeeping, security and others. Training will be provided in the form of lectures, formal course work, and demonstrations appropriate to the subject covered.

Personnel will be properly instructed:

a. Before assuming duties with, or in the vicinity of radioactive materials.

b. During annual refresher training.

c. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction to personnel will include the following subjects:

a. All terms of the license pertinent to their duties.

b. Areas where radioactive material is used or stored.

c. Potential hazards associated with radioactive material in each area where the employees work.

d. Radiological safety procedures appropriate to their respective duties.

e. Pertinent Kentucky Administrative Regulations, 902 KAR 100.

f. Licensee's in-house work rules.

g. Obligation to report unsafe conditions to the radiation safety officer.

h. Appropriate response to emergencies or unsafe conditions.

i. Right to be informed of their radiation exposure and bioassay results.

j. Locations where the licensee has posted, or made available, notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 902 KAR 100:165.

APPENDIX 0
(902 KAR 100:073, Section 4)

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

_____
(Licensee's Name)

_____
(Date)

1. Management Commitment

   a. We, the management of this (medical facility hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) (not required for a private practice physician) and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

   c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee (RSC)
   (The RSO on private practice physician licenses will assume these duties.)

   a. Review of Proposed Users and Uses

      (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of radioactive material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

(3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

(1) The RSC will delegate authority to the RS0 for enforcement of the ALARA concept.

(2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will, with the assistance of the RSO, perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceed (see Section 6).

(3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Review of specific procedures may be conducted on a more frequent basis.

(2) Quarterly review of occupation exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to

determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.

(3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Review Instances of Deviation from Good ALARA practices

The RSO will investigate all known instances of deviation from good ALARA practices and, If possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

(1) The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

(2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of Authorized User to Persons Under His/Her Supervision

(1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.

(2) The authorized user will ensure that persons under his/her supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Persons Who Receive Occupational Radiation Exposure

a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.

b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures

This Institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table O-1 below. These levels apply to the exposure of individual workers.

Table 0 -1

		Investigational Levels (mrems per calendar quarter) Level I	Level II
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625
3.	Skin of whole body*	750	2250

*(Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting isotopes.)

The following actions will be taken at the Investigational Levels as stated in Table O-1:

a. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 0 -1 values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's NRC Form 5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this Institution for review. The minutes, containing details of the investigation, will be made available to Cabinet inspectors for review at the time of the next inspection.

d. Reestablishment of an individual occupational worker's Investigational level II to a level above that listed in Table O-1.

In cases where a worker's or a group of workers' exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. Signature of Certifying Official

This signature is by a person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of a private practice, the licensee physician.

_____
Signature

_____
Name (print or type)

_____
Title

Institution (or Private Practice) Name and Address:

_____
_____
_____

APPENDIX P

MODEL PROCEDURE FOR CHECKING EQUIPMENT USED IN MOBILE NUCLEAR MEDICINE SERVICE (902 KAR 100:073, Sections 11 and 26)

The Cabinet normally limits its review of equipment quality assurance programs to those programs developed for radiation safety equipment. However, when delicate imaging equipment is transported from one location of use to another, e.g., by a mobile nuclear medicine service, it is reasonable to assume that it may suffer damage in transit. Therefore, the Cabinet requires that mobile nuclear medicine services have an imaging equipment quality assurance program to ensure that the use of byproduct material will not be inimical to the public health and safety.

You may use the following procedure to ensure the proper operation of imaging equipment that has been transported. If you follow the procedure, you may say on your application, "We will establish and implement the model procedure for ensuring equipment performance that was published in Appendix P to 'Medical Programs Licensing Guide, Revised March 2000."

If you want to develop your own procedure for review, you should consider for inclusion all the features in the model procedure and the procedure recommended by the manufacturer and carefully review the requirements of 902 KAR 100:073, Sections 11 and 26.

MODEL PROCEDURE

Survey Meter

Check the survey meter with the dedicated check source at each location of use. Material may not be used if the survey meter is not working. There is no need to keep a record of these checks.

Camera

1. Perform the following checks daily at each location of use before administering byproduct material:

    a. Peak each camera according to the manufacturer's instructions.

    b. Using either Tc-99m or Co-57, perform an extrinsic flood field with a frequently used collimator in place, or perform an intrinsic flood field test. Accumulate at least 1,000,000 counts for small-field-of-view cameras and 3,000,000 counts for large-field-of-view cameras. Process the image as if it were an image of a patient.

    c. Do not administer material until an authorized user or a designated technologist approves the camera for use.

    d. You do not have to make a permanent record of these daily checks.

2. Perform the following checks weekly:

    a. With the same frequently used collimator in place, image a flood source and either a parallel-line-equal-space (PLES) bar, orthogonal hole (OH) or resolution-quadrant phantom with the flood field as a source.

    b. If a PLES or bar phantom is used, rotate it 90° so that the camera is tested for both vertical and horizontal geometric linearity.

    c. If a resolution-quadrant phantom is used, rotate it so that each quadrant is imaged in each quadrant of the crystal. Then turn it over and again image it four more times. This procedure will check both resolution and horizontal and vertical geometric linearity in each quadrant of the crystal.

    d. Process the images as if they were images of a patient. Mark them clearly to indicate image orientation, source activity, and date.

    e. Retain the images for 2 years.

3. Perform the following safety checks after repairs and quarterly:

    a. Check the motion interlocks by activating the emergency-off switches on the camera. With the camera in motion, activation of the emergency-off switch should stop the motion. If this might jeopardize imaging components in the system, perform only the checks described in paragraph 3.b.

    b. Check the motion switches. Put the camera in motion and first release just the direction switch to stop the motion. Then put the camera back in motion and release just the dead-man switch. Test all motion switches and all directions in this manner. Release of either the motion switch or the dead-man switch alone should disable the camera motion. If this is not the case, repair the camera before clinical use.

4. Set the equipment in the same manner each time checks are run. Make a record of all these checks. Retain the record for 2 years.

APPENDIX Q

MODEL PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM
(902 KAR 100:019, Section 13)

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may indicate on your application, "We will establish and Implement the model personnel external exposure monitoring program published in Appendix Q 'Medical Programs Licensing Guide, Revised March 2000."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program and carefully review the requirements of 902 KAR 100:019, Section 13.

MODEL PROGRAM

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a regular basis.

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for such patients.

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages, will not normally be issued exposure monitors.

APPENDIX R

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES
(902 KAR 100:073, Section 19)

You or your consultant may use the following model procedure to leak-test sealed sources. If you, or the consultant, follow the model procedure you may indicate on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix R to 'Medical Programs Licensing Guide, Revised March 2000."

You may develop your own procedure for review. If you do, you should consider for inclusion all the features in the model and carefully review the requirements of 902 KAR 100:073, Section 19.

MODEL PROGRAM

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

    a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

    b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.

    c. If you are testing radium sources at the same time you are testing other licensed sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

4. The samples will be analyzed as follows:

    a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

    b. To estimate the detection efficiency of the analyzer used to assay the wipe. samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If

calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.

c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

d. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.

e. Continue the same analysis procedure for all wipe samples.

f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under a NRC or Agreement State license, the Cabinet must be notified. (See 902 KAR 100:073, Section 19 (5).

g. Sign and date the list of sources, data, and calculations.

APPENDIX S

RECORDS OF RADIOACTIVE MATERIAL USE
(902 KAR 100:073, Section 17 and 100:042, Section 11)

General

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in these procedures. Also, you do not have to replicate entries. For example, if you prepare a multidose vial for use one day, you do not have to record the date each time you draw a dosage from it; if you take 30 Ir-192 seeds that are each 0.5 millicuries, you do not have to list each seed individually.

S.l Records of Unit Dosage Use (902 KAR 100:073, Section 17)

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may indicate on your application, "We will establish and Implement the model procedure for a unit dosage record system that was published in Appendix S.l to 'Medical Programs Licensing Guide, Revised March 2000."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 902 KAR 100:073, Section 17.

MODEL PROCEDURE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;

2. Generic name or its abbreviation or trade name;

3. Date of receipt;

4. Supplier;

5. Lot number or control number, if assigned;

6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;

7. Date of administration or disposal;

8. If administered,

    a. Prescribed dosage (unless already recorded in clinical procedure manual),

b. Measured activity in millicuries or microcuries and date and time of measurement,

c. Patient name and identification number if one has been assigned;

9. If discarded, the date and method of disposal; and

10. Initials of the individual who made the record.

S.2 Records of Multidose Vial Use (902 KAR 100:073, Section 17)

You may use the following model procedure to keep a record of multidose vial use. If you will follow the model procedure, you may indicate on your application, 'We will establish and implement the model, procedure for a multidose vial record system that was published in Appendix S.2 to 'Medical Programs Licensing Guide, Revised March 2000.'

If you prefer, you may develop your own multidose vial record system for review. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of 902 KAR 100:073, Section 17.

MODEL PROCEDURE

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide;

2. Generic name or its abbreviation or trade name;

3. Date of receipt or preparation;

4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);

5. Supplier or kit manufacturer;

6. If administered,
   a. Prescribed dosage (unless already recorded in clinical procedure manual),
   b. Date and time dosage was drawn and measured,
   c. Calculated volume that is needed for the prescribed dosage,
   d. Measured activity in millicuries or microcuries,
   e. Patient name and identification number if one has been assigned;

7. If discarded, the method of disposal and date; and

8. Initials of the individual who made the record.

S.3 Measuring and Recording Molybdenum Concentration (902 KAR 100:073, Section 32)

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration. (This does not have to be done when using radiopharmaceuticals obtained from a distributor.) This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of administration.

The model procedure for measuring molybdenum concentration is based on the use of a "molybdenum breakthrough pig." Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99m generator elution. If you will follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published Appendix S.3 to "Medical Programs Licensing Guide, Revised March 2000."

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 902 KAR 100:073, Section 32.

MODEL PROCEDURE

Each time a generator is eluted, make a record of the:

1. Date the generator was received;

2. Date and time of elution;

3. Measured Mo-99 activity in microcuries;

4. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;

5. Measured Tc-99m activity in millicuries;

6. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and check mark that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. (If it isn't, stop and notify the RSO. In conformance with 902 KAR 100:073, Section 32 (4), the licensee must notify the Cabinet if a leaking generator is detected.) (The 0.07 action level allows for the quicker decay of the Tc through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Mo-99 to Tc-99m would have doubled.)

7. Initials of the person who made the record.

S.4 Keeping an Inventory of Implant Sources (902 KAR 100:073, Section 44 and 100:042, Section 11)

You may use the following model procedure to keep an inventory and use record for implant sources. If you will follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix S.4 to 'Medical Programs Licensing Guide, Revised March 2000."

If you prefer, you may develop your own procedures for keeping an inventory and use record for implant sources. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of 902 KAR 100:073, Section 44.

MODEL PROCEDURE

1. Use a locking installed cabinet or safe to store all implant sources.

2. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.

3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.

4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.

5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's name, and the time and date they were removed from storage; initial the record.

6. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage; initial the record.

7. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

APPENDIX T
MOBILE NUCLEAR MEDICINE REQUIREMENTS
(902 KAR 100:073, Section 11)

1. A complete application in accordance with the enclosed medical licensing guide.

2. A complete description of the services to be furnished at each hospital.

3. A statement from each hospital administrator granting approval for use of radioactive material at his/her facilities; and confirmation that the hospital does not have an active Kentucky Radioactive Material License.

4. Confirmation that a physician shall be on-site at the time that radiopharmaceuticals are administered. The identity of this on-site physician must be included on your license application and this physician must have at least (30) hours of training in basic radiological handling techniques.

5. Confirmation that all doses will be assayed prior to transport, if you will not have a dose calibrator at the hospitals you intend to service.

6. A description of your procedures for transporting the radioactive materials. Include shielding requirements and emergency procedures. Also indicate the area in the vehicle where the radioactive materials will be stored. (This location should be away from the passenger compartment.)

7. A description of the procedures for ensuring that radioactive materials, located in the van, will be secured at all times.

8. A description of the training that will be provided to the drivers of the vehicles used for transporting the radioactive materials. (Note that their training should include all items specified in 902 KAR 100:165, Section 2 as well as instructions for handling spills and other emergencies.)

9. A description of the area in each hospital where nuclear medicine procedures will be performed.

10. Confirmation that all diagnostic instrumentation transported by van shall be calibrated at each location of use prior to conducting nuclear medicine procedures.

11. Confirmation that a contamination survey will be performed at each location of use and that all sources of licensed material and all detectable contamination will be removed after each use.

12. Confirmation that radioactive material will not be stored in the van overnight, and that after each day's use, the van will be monitored for contamination.

13. Confirmation that all radioactive materials transported will be received at the "base station" hospital under the terms and conditions of the hospital's Kentucky Radioactive Material License.

14. Because of the radiation safety problems associated with the use of radioactive gases, Xenon-l33 has not been authorized for mobile nuclear medicine services.

APPENDIX U

GUIDANCE ON COMPLYING WITH 902 KAR 100:019 REQUIREMENTS
Guide for the Preparation of Applications for Medical Programs

The revision of Kentucky Administrative Regulation 902 KAR 100:019, Standards for Protection Against Radiation, changes a number of the requirements for medical use programs. The major change is to incorporate newer national and international concepts on radiation protection, including the application of a risk-based approach to the establishment of radiation protection limits. Included are the adoption of the "effective dose" concept, specification of occupational dose limits as the sum of internal and external dose, and use of annual limits on intake (ALIs) and derived air concentrations (DACs) as a means for regulating the ingestion and inhalation of radionuclides.

The adoption of the effective dose concept and the application of the occupational dose limit to the sum of the internal and external doses change the methodology to be used for evaluating, controlling, and recording radiation doses. In addition to the changes to the dose methodology, there are other differences between the provisions of the old 902 KAR 100:020 and the provisions of 902 KAR 100:019.

Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Cabinet's regulations, the methods described in this guide will be used in the evaluation of applications for new licenses or license renewals and for evaluating compliance with 902 KAR 100:019.

This new appendix discusses the major differences introduced by 902 KAR 100:019 that modify the guidance previously provided by the Cabinet for the conduct of medical use programs.

Any information collection activities mentioned in this appendix are contained as requirements in the regulations which provide the regulatory basis for this guide.

The following are the major areas of medical use programs affected by regulation 902 KAR 100:019.

1. RADIATION PROTECTION PROGRAMS (See Appendix 0 to the Licensing Guide)

In 902 KAR 100:019, Section 2 each licensee is required to develop document, and implement a radiation protection program appropriate to the scope and extent of the activities conducted and to review at least annually the program content and its implementation. Further. 902 KAR 100:019, Section 2 requires that each licensee use engineering controls and procedures to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). In addition. 902 KAR 100:019, Section 30 provides the recordkeeping requirements for radiation protection programs.

The requirements in 902 KAR 100:019, Section 2 are consistent with the requirements for control of occupational exposures in 902 KAR 100:052 and 073. Radiation protection programs that have been established under the requirements of these regulations will be considered to be acceptable to meet the occupational ALARA requirements of 902 KAR 100:019, Section 2 when the program activities are limited to external occupational exposures. However licensees who handle unsealed radioactive materials that may cause internal exposure to members of the public will need to supplement their ALARA programs to address potential internal as well as external doses to members of the general public from effluents to unrestricted areas. Additional guidance is published in NRC Regulatory Guide 8.37 " ALARA Levels for Effluents from Materials Facilities." Licensees should establish ALARA goals or objectives for effluents.

In developing an ALARA radiation protection program, licensees should design the program based on the size of the licensed facility. The potential hazards associated with radiation exposure, the potential intake of radioactive material, and the physical characteristics of the radionuclides (i.e.. solid, liquid, or gas). For example, the magnitude of an ALARA program for a large research hospital would be expected to be considerably more comprehensive in scope than a radiation protection program for a private practice physician. The program should include the mechanisms for periodic (at least annually) review of performance, as well as actions to be taken when ALARA goals or objectives are not met.

902 KAR 100:019 does not require that a numerical cost-benefit analysis (quantitative approach) be used to demonstrate ALARA. However, the Radiation Health & Toxic Agents Branch encourages medical licensees to use quantitative analyses in developing ALARA programs and procedures. If it can be performed readily, licensees should demonstrate through quantitative analysis that the cost and benefits associated with design, engineering controls, and operating procedures have been optimized in accordance with the ALARA principle. If a quantitative analysis cannot be readily performed, licensees should thoroughly evaluate any design or engineering controls that may need to be changed to keep operating procedures ALARA.

Examples of the type of ALARA optimization considerations appropriate to the conduct of medical use programs are presented in the National Council on Radiation Protection and Measurement (NCRP) Report No. 107, "Implementation of the Principle of As Low As Is Reasonably Achievable (ALARA) for Medical and Dental Personnel,"* December 31, 1990. This NCRP report provides specific hypothetical examples of optimization decisions in implementing ALARA in nuclear medicine and radiation oncology.

*NCRP reports can be purchased by writing to NCRP Publications. 7910 Woodmont Avenue. Suite 800. Bethesda, MD 20814.

2. INTERNAL DOSE METHODOLOGY

902 KAR 100:019 incorporates the new dose methodology system developed by the International Commission on Radiological Protection (ICRP) which specifies radiation dose limits in terms of an "equivalent" whole body dose, taken to be the sum of individual organ committed doses weighted by the risk of biological effect for each of the organs irradiated. This effective dose equivalent concept is used to control the stochastic biological effects of exposure to ionizing radiation. Nonstochastic or threshold, biological effects are avoided by establishing dose limits for the committed dose received by an individual organ and for the exposure to the skin and to the lens of the eye (902 KAR 100:019, Section 3).

2.1 Units and Terms for Internal Exposure

902 KAR 100:019 uses the "special" units of dose and activity and presents the corresponding values for the international system (SI). Records and reports required under 902 KAR 100:019 are to be maintained using the "special" units.

The following table provides the conversions between the two systems of measurement:

<u>Special Units</u>	
(Activity) curie (Ci)	=3.7 x 10^{10} disintegrations per second = 3.7 x 10^{10} Bq
(Absorbed dose) rad	= 100 ergs/gram (0.01 Gy)
(Dose equivalent) rem	= Quality factor x rad (0.01 Sv)
<u>SI Units</u>	
(Activity) becquerel (Bq)	= 1 disintegration per second (2.7 x 10^{-13} Ci)
(Absorbed dose) gray (Gy)	= joule/kg (100 rads)
(Dose equivalent) sievert (Sv)	= Quality factor x grays (100 rems)

In addition, new terms are introduced for radionuclide intakes by means of inhalation and ingestion, e.g., derived air concentration (DAC). For a few radionuclides (e.g.. noble gases such as xenon), the terms apply to exposures from submersion.

The new term DAC is used, in broad terms, similar to the way in which the maximum permissible concentration (MPC) was used in 902 KAR 100:020. Exposure to airborne radioactivity at a level of 1 DAC for 1 year (2000 hours) would result in either a committed effective dose equivalent of 5 rems (50 mSv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. In order to show compliance with the occupational dose limit of 5 rems (50 mSv), a facility must consider the contributions of internal and external doses prior to calculating ventilation and gas clearance time.

Appendix M to the Licensing Guide provides model procedures for calculating worker doses from concentrations of gases in work areas and for calculating spilled gas clearance times. The procedure states that the MPC values for the radionuclide of interest should be used in the calculations. To implement the new regulation, the DAC value for the radionuclide of interest, in conjunction with the contribution of external dose, must be used instead of the MPC value. For example, consider the following simplified approach to determining required ventilation rates in an area where xenon-133 procedures will be performed:

Example:

A new room is being designed in an existing nuclear medicine department where xenon-133 ventilation studies will be performed. You are asked to calculate the minimum ventilation rates required to maintain compliance with the occupational dose limits.

1. Determine the highest dose to an individual from all external radiation for the previous 12 month period by reviewing personnel monitoring records (film, TLD, etc.). If necessary, modify the dose to account for an anticipated increase or decrease in patient workload.

2. Modify the DAC value for xenon-133 to allow for the estimated annual external exposure. A simplified method is to subtract the estimated external dose from the occupational dose limit of 5 rems (50 mSv) and divide this number by 5 rems.

This yields the fraction of the dose limit of 5 rems that would still be permitted from internal sources. Multiplying this fraction times the DAC value yields a modified DAC. These DAC values are provided in 902 KAR 100:019, Section 44, Table 1, Column 3.

The annual external dose is 2 rems. The listed DAC value for xenon-133 is 1E-4 mCi/mi. The modified DAC value should be based on 3 rems that could still be incurred from internal exposure.

3. Calculate the minimum ventilation rates for the room using the procedure provided in Appendix M to this Licensing Guide. In place of the MPC value stipulated in Appendix M, use the modified DAC value. In the example provided above, the modified DAC value (6E-5 mCi/ml) would be used instead of the MPC value for xenon-133.

The discussion and example presented in this section do not specifically address ALARA and the monitoring thresholds for internal doses as it relates to the summation of internal and external dose. However, it should be noted that modifications to ventilation rates can be a means to maintaining exposures ALARA. In addition, increased ventilation rates may negate the requirement to monitor internal dose and, as such, may eliminate the necessity to sum internal and external dose to show compliance with the occupational dose limits.

2.2 Occupational Dose Limits

In 902 KAR 100:020, Section 2, the quarterly occupational dose limit of 1.25 rems (5 rems in a year) applied only to whole body exposures to external radiation. If the licensee had a dose history and a worker's cumulative dose is less than 5(age-18) rems, the worker could have been allowed under certain circumstances to receive occupational exposure in excess of the 902 KAR 100:020 limit up to 3 rems per quarter. In addition to the 5 rem annual total for occupational external exposure, 902 KAR 100:020 specified a separate limit to apply to exposures to concentrations of radioactive materials in air in restricted areas (902 KAR 100:020 and 902 KAR 100:025).

902 KAR 100:019 applies the 5 rem (50 mSv) occupational dose limit as a whole body "effective" dose. This limit is the sum of the deep-dose equivalent from external sources and the committed effective dose equivalent to the organs exposed from the internal uptake of radionuclides, expressed as the total effective dose equivalent (902 KAR 100:019, Section 3). Additional guidance is provided in the NRC guide, "Monitoring Criteria and Methods To Calculate Occupational Doses," on the methods to be used for determining these dose equivalents. Revision 1 of the guide, "Instructions for Recording and Reporting Occupational Radiation Exposure Data," provides guidance on reporting the dose data on NRC Forms 4 and 5. 902 KAR 100:019 no longer contains provisions for an age proration 5(N-18).

2.3 Effective Dose Equivalent

The effective dose equivalent concept described above makes it possible to combine both the internal and external doses in assessing the overall risk of health effects to an individual. Prior to the adoption of 902 KAR 100:019 the activity concentration limits for intakes of a single radionuclide (in 902 KAR 100:025) were based on controlling the dose to the organ receiving the highest dose ("critical organ"). These concentration limits, however, were treated separately from the dose limits for external exposure. 902 KAR 100:019 dose methodology evaluates the doses to all major body organs, multiplies these doses by the appropriate organ weighting factors, and then sums the organ-weighted doses to obtain a whole body "risk-weighted effective dose." The ALIs and DACs in 902 KAR 100:019, Section 44, therefore, reflect the doses to all principal organs that are irradiated, not just the one organ that receives the highest dose, as was done previously.

3. DECLARED PREGNANT WOMEN [Embryo/Fetus Dose Limits] (See 902 KAR 100:010 and 902 KAR 100:019, Section 9)

902 KAR 100:019 uses the term "declared pregnant woman" to mean a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

For declared pregnant women, the Cabinet limits the dose to the embryo/fetus to 0.5 rem (5 mSv) over the entire pregnancy. In addition, the licensee is required to make an effort to avoid substantial variation above a uniform monthly exposure rate (0.05 rem/month) (0.5 mSv/month). Declared pregnant women are not allowed to receive planned special exposures that involve whole body doses or maternal intakes that could result in exceeding the embryo/fetus dose limit.

The radiation protection program should make provisions for instructing women workers about the special need to protect the embryo/fetus and to encourage them to promptly notify their employer if they become pregnant. The NRC guide "Radiation Dose to the Embryo/Fetus," contains guidance on evaluating the dose to the embryo/fetus.

4. LEVELS IN UNRESTRICTED AREAS
(See 902 KAR 100:019, Sections 10 and 11)

902 KAR 100:019 uses the following terms, as defined in 902 KAR 100:010, with regard to areas with or without radiological restrictions:

"Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

"Entrance or access point" means a location through which an individual may gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"Radiation area" means an area, accessible to individuals, in which there exists radiation at levels that an individual may receive in excess of 5 mrem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from a surface that the radiation penetrates.

"Restricted area" means an area, access to which is limited by the licensee for purposes of protecting individuals against undue risks from exposure to radiation and radioactive materials. A restricted area shall not include areas used as residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

"Unrestricted area" means an area, access to which is not limited nor controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive material.

The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted to 2 mrem (20 mSv) in any 1 hour from external sources and to 100 mrem (1 mSv) in a year total effective dose equivalent for individual members of the public. Depending on how the licensee's hospital areas are controlled and monitored, hallway areas outside patient therapy rooms and diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.

5. NVLAP PROCESSORS
(See 902 KAR 100:019, Section 12)

Personnel dosimeters that require processing to determine the dose to compare to the 902 KAR 100:019 dose limits must be processed and evaluated by a dosimetry processor that is accredited under the National Voluntary Laboratory Accreditation Program (NVLAP).

6. CONTROL OF LABORATORIES
(See 902 KAR 100:019. Sections 2, 17, 21. 22 and 24)

Access to laboratories using radionuclides as well as the work practices in these laboratories, need to be controlled. Controlling access to radionuclide laboratories is accomplished by posting the entrance door and locking all accessible entrances to the laboratory when an authorized user, or an individual under the supervision of an authorized user, is not present. An acceptable alternative is to provide lockable storage facilities within the laboratory. In 902 KAR 100:019, Section 24(5), posting is required for each area or room in which there is used or stored a quantity of licensed material exceeding 10 times the quantity in 902 KAR 100:030. Some of the 902 KAR 100:030 quantities will be changed. Appendix G to the Medical Licensing Guide provides model rules for safe use of radiopharmaceuticals that can be used for radionuclide laboratories, and Appendix H provides model spill procedures.

7. POSTING AND CONTROLLING ACCESS TO PATIENT ROOMS (See 902 KAR 100:019, Section 25(2))

When patients have received therapeutic administrations of radionuclides or therapeutic applications of sealed sources, the criteria for exceptions to posting requirements specified in 902 KAR 100:019, Section 25 will likely be exceeded. Dose rates from therapy patients can often exceed 5 mrem (50 mSv) per hour at 1 meter from the patient. Under these conditions, the entrance to the patient's room must be posted and access to the area controlled. Access can be controlled by routine surveillance and by posting instructions for hospital personnel and visitors at the entrance to the patient's room. Examples of such instructions can be found in Exhibit 9 of the licensing guide. Systems such as remote TV surveillance, electronic eye, or personnel entry detection devices are considered acceptable for monitoring personnel access to the patient's room.

Note that 902 KAR 100:019, Section 25 allows exceptions to the posting requirements if specific conditions are met. Licensees should review 902 KAR 100:019, Sections 24 and 25 for posting requirements since some of the posting language has changed.

8. EXEMPTIONS TO LABELING REQUIREMENTS (See 902 KAR 100:019, Section 27)

Licensees are not required to label containers holding licensed material in quantities less than the quantities listed in 902 KAR 100:030. For iodine 125, carbon-14, and sulfur-35, the quantities below which labeling is not required are 1 uCi, 1000 uCi, and 100 uCi, respectively. In addition, licensees are not required to label containers holding licensed material in concentrations less than those specified in Table 3 of Section 44 to 902 KAR 100:019. For

iodine-125, carbon-14, and sulfur-35, the exempt concentrations are 2E-5 uCi/ml, 3E-4 uCi/ml. and 1E-3 uCi/ml, respectively.

9. PROCEDURES FOR RECEIVING AND OPENING PACKAGES (See 902 KAR 100:019, Section 28(3) and (4))

902 KAR 100:019. Section 28 modifies the Type A package quantity limits affecting package opening procedures, monitoring required for radioactive contamination on external surfaces of a package, and surface contamination levels requiring notification of the Radiation Health & Toxic Agents Branch as follows: Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in 902 KAR 100:070 (e.g.. more than 13.5 curies of molybdenum-99; 216 curies of technetium-99m; 13.5 curies of iodine-131, cesium-137, or iridium-192; or more than 54.1 curies of iodine-125). All shipping packages received, known to containing radioactive material or if there is evidence of damage to the package. Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours, or within 3 hours from the beginning of the next working day if received after working hours, in accordance with the requirements of 902 KAR 100:019, Section 28. The Radiation Health & Toxic Agents Branch and the final delivery carrier must be notified immediately if removable contamination or the external radiation levels exceed the limits of 902 KAR 100:070. Note that these Appendix U procedures for receiving and opening packages do not exempt packages containing less than Type A quantities of radioactive material from removable contamination surveys as did 902 KAR 100:035 and Appendix F to this licensing guide. Therefore, it may be necessary for a licensee to revise current package opening procedures to reflect the changes in 902 KAR 100:019.

10. EFFLUENT RELEASES TO SEWER

902 KAR 100:021, Section 3 allows licensees, under certain quantity release constraints, to discharge licensed material into sanitary sewers if the material is readily soluble in water or if the material is readily dispersible biological material. Dispersible in this context means able to be distributed as particles, more or less evenly throughout a medium, such as a sewer system. In practical terms, biological material should be divided finely enough so as to mix readily with a water stream and continue to disperse rather than to reconcentrate. This provision of the revised 902 KAR 100:021 allows continuation of the practice of discharging readily dispersible biological materials such as ground-up animal carcasses. The prohibition of the discharge to sanitary sewer systems of non-biological insoluble materials by the regulation was designed to minimize the accumulation of insoluble material in the sewer system, treatment plant, and in sewage sludge. Licensees should note that the monthly average concentrations of radionuclides allowed to be released to sanitary sewers under 902 KAR 100:021 and Table 3 of 902 KAR 100:019, Section 44 are, generally 10 times more restrictive than the monthly average concentrations that have been allowed to be released into sanitary sewer systems under 902 KAR 100:025. In addition, the licensee should note that there are no longer daily concentration limits for release of material to the sanitary sewer as discussed in Appendix J to this licensing guide.

APPENDIX V

QUALITY MANAGEMENT PROGRAM
(902 KAR 100:073, Section 9)

The purpose of a quality management program (QMP) is to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. A properly administered QMP will reduce the occurrences of misadministrations and recordable events.

A written quality management program is required for any radiation program that administers:

1. Quantities greater than 30 μCi of sodium iodine I-125 or I-131;
2. A therapeutic radiopharmaceutical other than sodium iodine I-125 or I-131.
3. A brachytherapy radiation dose;
4. A gamma stereotactic radiosurgery radiation dose;
5. A teletherapy radiation dose.

Model procedures for stereotactic radiosurgery and teletherapy are not included with this appendix because of each institution's special requirements. When submitting your QMP for these activities, you should carefully review the requirements of 902 KAR 100:073, Section 9.

V.1 ADMINISTRATION OF QUANTITIES GREATER THAN 30 μCI OF EITHER SODIUM IODINE I-125 OR I-131

You may use the following program for your quality management program. If you follow the guidance in the program, you may indicate on your application, "We will establish and implement the model quality management program published in Appendix V.1 to Medical Programs Licensing Guide, Revised July 2000."

If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program and carefully review the requirements of 902 KAR 100:073, Section 9.

I. MODEL PROCEDURE

1. Authority, Responsibility, and Review.

   A. The authority and responsibility to establish and implement the Quality Assurance Program (QMP) shall be given to the Radiation Safety Officer (RSO).

2. Policy Regarding Elements for Administering

   A. Prior to administration, a written directive issued by an authorized user will be prepared for any administration of sodium iodine I-125 or I-131 in quantities greater than 30 μCi. A written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical. The written directive should contain the following information:

      1. Patient's name
      2. Patient identification number, if available
      3. Radiopharmaceutical
      4. Dosage
      5. Route of administration
      6. The type of procedure desired
      7. Date
      8. Signature of authorized user

Except in emergent situations as defined in subsection E, no radioiodine I-125 or I-131 in quantities greater than 30 μCi shall be administered by any personnel in the absence of a signed directive with the above elements.

   B. Prior to administration, the patient's identity is verified by more than one method as the patient named in the written directive. The person responsible for the administration of the radiopharmaceutical will complete the verification. Verification of identity must include at least two of the following methods:

1. The patient shall be asked to state and spell their name.
2. The patient shall be asked to state their birth date.
3. The patient shall be asked to state their social security number.
4. The patient shall be asked to state their address.
5. The patient shall be asked for identification, i.e. driver's license.
6. The patient's wrist identification band shall be checked for name and patient number.
7. For patients unable to respond, an accompanying relative or friend may attest to the patient's identity. Record name and relationship of same.

If the information obtained from any two of these methods does not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification is obtained.

C. Each administration must be in accordance with the written directive. The physician or nuclear medicine technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear, the specific authorized user must be contacted to provide clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the person administering the dose. If the person preparing the dose is different from the one administering the dose, both shall read and understand the written directive. The persons who prepare and administer the dose shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directive. The actual dose calibrator assay shall be verified with the dosage listed on the written directive.

D. Each administration must have a written protocol. A procedure manual shall be available and shall contain protocols for all radiopharmaceutical procedures performed which require written directives. A procedure, which requires a written directive, shall not be initiated until a written protocol approved by an authorized user is available. The nuclear medicine physicians and technologists shall be familiar with the contents of the manual. They shall be instructed to refer to the manual before proceeding with non-routine procedures or in any case where the protocol is not completely familiar to them. The protocol shall contain the following elements:

1. Pharmaceutical
2. Radionuclide
3. Routine dosage
4. Route of administration
5. Indications
6. Contraindications

Any change in protocol shall be approved by an authorized user before that change is implemented and always before the change is incorporated into the procedure manual. Each person who prepares and administers radiopharmaceuticals shall be instructed in the change before it is implemented or incorporated into the procedure manual.

E. Oral directives are permissible only when a patient's medical condition is such that their health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives are employed, the information contained in the oral directive is immediately documented in the patient's record and the original written directive is prepared within 24 hours of the oral issue. In the situation of an oral revision of an existing written directive, it must be revised, dated and signed by the authorized user within 48 hours of the oral revision.

F. Following administration of the radiopharmaceutical dose, a dated and signed written note is entered into the patient's record documenting the administration and dosage.

G. If any unintended deviation from the written directive is identified, it is evaluated and appropriate action taken. Upon identification of an unintended deviation, whether a recordable event or a misadministration, an investigation of the incident shall be made. The cause of the incident shall be determined and, if appropriate, corrective procedures will be implemented. Documenting and reporting of the unintended deviation shall be in accordance with the reporting rules of 902 KAR 100:073, Section 12.

H. An annual review shall be conducted by the radiation safety officer or by quality management personnel. Using pre-established criteria, the review shall determine the effectiveness of this quality management program. Areas identified as inadequate as determined by failure to meet 100% compliance shall be modified to meet the objectives of 902 KAR 100:073, Section 9. Records of each review, including the evaluations and findings in an auditable form are to be saved for three years. These records may be reviewed during the next regulatory inspection.

I. Review protocol:

Frequency: A review of the quality management program shall be conducted at 12 month intervals with the written summary report presented to the radiation safety committee.

Scope: The review shall evaluate 100% compliance with the following criteria:

1. Having written directives prior to administration of radiopharmaceuticals.
2. Oral directives are reserved for emergent situations where delay would jeopardize the patient's health.
3. The content of the written directive is as required.
4. All individuals involved in the preparation or administration of radioiodines have received instruction in the requirements of this quality management program and documentation of the training is available.
5. More than one method of verifying the patient's identity is performed prior to administration of the radioiodine.

6. Radiopharmaceutical administration are in accordance with the specific information contained in the written directive.
7. Unintended deviations from the written directive are identified, evaluated, and appropriate corrective actions instituted.
8. Each recordable event evokes the proper response.
9. Appropriate persons (e.g. authorized user and referring physician) notified and misadministrations reported.
10. Appropriate records kept, including the annual reviews, written directives, radiopharmaceutical dosages, recordable events, and misadministrations.

J. Procedures specified in this document will be implemented prior to administration of any radiopharmaceuticals containing sodium iodine I-125 or I-131 in quantities greater than 30 μCi to patients.

V.2 ADMINISTRATION OF THERAPEUTIC DOSES OF RADIOPHARMACEUTICALS OTHER THAN SODIUM IODINE I-125 OR I-131

You may use the following program for your quality management program. If you follow the guidance in the program, you may indicate on your application, "We will establish and implement the model quality management program published in Appendix V.2 to Medical Program Licensing Guide, Revised July 2000."

If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program and carefully review the requirements of 902 KAR 100:073, Section 9.

II. MODEL PROCEDURE

1. Authority, Responsibility, and Review.

    A. The authority and responsibility to establish and implement the Quality Assurance Program (QMP) shall be given to the Radiation Safety Officer (RSO).

2. Policy Regarding Elements for Administering

    A. Prior to administration, a written directive issued by an authorized user will be prepared for any therapeutic administration of a radiopharmaceutical. A written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical. The written directive should contain the following information:

        1. Patient's name
        2. Patient identification number, if available
        3. Radiopharmaceutical
        4. Dosage
        5. Route of administration
        6. The type of procedure desired
        7. Date
        8. Signature of authorized user

Except in emergent situations as defined in subsection E, no therapeutic radiopharmaceuticals shall be administered by any personnel in the absence of a signed directive with the above elements.

    B. Prior to administration, the patient's identity is verified by more than one method as the patient named in the written directive. The person responsible for the administration of the radiopharmaceutical will complete the verification. Verification of identity must include at least two of the following methods:

1. The patient shall be asked to state and spell their name.
2. The patient shall be asked to state their birth date.
3. The patient shall be asked to state their social security number.
4. The patient shall be asked to state their address.
5. The patient shall be asked for identification, i.e. driver's license.
6. The patient's wrist identification band shall be checked for name and patient number.
7. For patients unable to respond, an accompanying relative or friend may attest to the patient's identity. Record name and relationship of same.

If the information obtained from any two of these methods does not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification is obtained.

C. Each administration must be in accordance with the written directive. The physician or nuclear medicine technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear, the specific authorized user must be contacted to provide clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the person administering the dose. If the person preparing the dose is different from the one administering the dose, both shall read and understand the written directive. The persons who prepare and administer the dose shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directive. The actual dose calibrator assay shall be verified with the dosage listed on the written directive.

D. Each administration must have a written protocol. A procedure manual shall be available and shall contain protocols for all radiopharmaceutical procedures performed which require written directives. A procedure, which requires a written directive, shall not be initiated until a written protocol approved by an authorized user is available. The nuclear medicine physicians and technologists shall be familiar with the contents of the manual. They shall be instructed to refer to the manual before proceeding with non-routine procedures or in any case where the protocol is not completely familiar to them. The protocol shall contain the following elements:

1. Pharmaceutical
2. Radionuclide
3. Routine dosage
4. Route of administration
5. Indications
6. Contraindications

Any change in protocol shall be approved by an authorized user before that change is implemented and always before the change is incorporated into the procedure manual. Each person who prepares and administers radiopharmaceuticals shall be instructed in the change before it is implemented or incorporated into the procedure manual.

E. Oral directives are permissible only when a patient's medical condition is such that their health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives are employed, the information contained in the oral directive is immediately documented in the patient's record and the original written directive is prepared within 24 hours of the oral issue. In the situation of an oral revision of an existing written directive, it must be revised, dated and signed by the authorized user within 48 hours of the oral revision.

F. Following administration of the radiopharmaceutical dose, a dated and signed written note is entered into the patient's record documenting the administration and dosage.

G. If any unintended deviation from the written directive is identified, it is evaluated and appropriate action taken. Upon identification of an unintended deviation, whether a recordable event or a misadministration, an investigation of the incident shall be made. The cause of the incident shall be determined and, if appropriate, corrective procedures will be implemented. Documenting and reporting of the unintended deviation shall be in accordance with the reporting rules of 902 KAR 100:073, Section 12.

H. An annual review shall be conducted by the radiation safety officer or by quality management personnel. Using pre-established criteria, the review shall determine the effectiveness of this quality management program. Areas identified as inadequate as determined by failure to meet 100% compliance shall be modified to meet the objectives of 902 KAR 100:073, Section 9. Records of each review, including the evaluations and findings in an auditable form are to be saved for three years. These records may be reviewed by the appropriate regulatory agencies.

I. Review protocol:

Frequency: A review of the quality management program shall be conducted at 12 month intervals with the written summary report presented to the radiation safety committee.

Scope: The review shall evaluate 100% compliance with the following criteria:

1. Having written directives prior to administration of radiopharmaceuticals.
2. Oral directives are reserved for emergent situations where delay would jeopardize the patient's health.
3. The content of the written directive is as required.
4. All individuals involved in the preparation or administration of therapeutic radiopharmaceuticals have received instruction in the requirements of this quality management program and documentation of the training is available.
5. More than one method of verifying the patient's identity is performed prior to administration of the radiopharmaceutical.
6. Radiopharmaceutical administrations are in accordance with the specific information contained in the written directive.

7. Unintended deviations from the written directive are identified, evaluated, and appropriate corrective actions instituted.
8. Each recordable event evokes the proper response.
9. Appropriate persons (e.g. authorized user and referring physician) notified and misadministrations reported.
10. Appropriate records kept, including the annual reviews, written directives, radiopharmaceutical dosages, recordable events, and misadministrations.

J. Procedures specified in this document will be implemented prior to administration of any therapeutic radiopharmaceuticals to patients.

V.3 ADMINISTRATION OF A BRACHYTHERAPY RADIATION DOSE

You may use the following program for your quality management program. If you follow the guidance in the program, you may indicate on your application, "We will establish and implement the model quality management program published in Appendix V.3 to Medical Program Licensing Guide, Revised July 2000."

If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program and carefully review the requirements of 902 KAR 100:073, Section 9.

III. MODEL PROCEDURE

1. Authority, Responsibility, and Review.

    A. The authority and responsibility to establish and implement the Quality Assurance Program (QMP) shall be given to the Radiation Safety Officer (RSO).

2. Policy Regarding Elements for Administrating

    B. Prior to administration, a written directive issued by an authorized user will be prepared for any brachytherapy radiation dose. A written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to the administration of brachytherapy dose. The written directive should contain the following information:

        1. Patient's name
        2. Patient identification number, if available
        3. Radioisotope
        4. Number of sources
        5. Dosage
        6. Treatment site
        7. Date
        8. Signature of authorized user

Except in emergent situations as defined in subsection E, no brachytherapy dose shall be administered by any personnel in the absence of a signed directive with the above elements.

    C. Prior to administration, the patient's identity is verified by more than one method as the patient named in the written directive. The person responsible for the administration of the radiopharmaceutical will complete the verification. Verification of identity must include at least two of the following methods:

        1. The patient shall be asked to state and spell their name.
        2. The patient shall be asked to state their birth date.
        3. The patient shall be asked to state their social security number.
        4. The patient shall be asked to state their address.

5. The patient shall be asked for identification, i.e. driver's license.
6. The patient's wrist identification band shall be checked for name and patient number.
7. For patients unable to respond, an accompanying relative or friend may attest to the patient's identity. Record name and relationship of same.

If the information obtained from any two of these methods does not correspond to the information on the written directive, the brachytherapy dose shall not be administered until conclusive verification is obtained.

D. Each administration must be in accordance with the written directive. A qualified individual shall read the written directive before preparing or administering the brachytherapy dose. A qualified individual includes radiation therapy physicist, oncology physicians, dosimetrists, or radiation therapy technologists. If any portion of the written directive is unclear, the specific authorized user must be contacted to provide clarification. The brachytherapy dose shall not be administered until the intent of the written directive is thoroughly understood by the personnel administering the dose. The specific details of the treatment plan shall be verified with the written directive by a qualified individual.

E. Oral directives are permissible only when a patient's medical condition is such that their health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives are employed, the information contained in the oral directive is immediately documented in the patient's record and the original written directive is prepared within 24 hours of the oral issue. In the situation of an oral revision of an existing written directive, it must be revised, dated and signed by the authorized user within 48 hours of the oral revision.

F. Radiographs or other comparable images (e.g., CT images) made with either the brachytherapy sources or non-radioactive "dummy" sources in place should be used as the basis for verifying the positions of the sources and calculating the treatment time. The use of dummy sources are preferred over active ones whenever possible. It is recognized that such images may not be necessary in certain procedures in which applicators are used, provided the source positions are known prior to inserting the active sources and calculating the treatment time.

G. After insertion of either permanent or temporary brachytherapy sources an authorized user will promptly record the actual loading sequence of the radioactive sources implanted and sign or initial the patient's chart or other appropriate record.

H. During the implant or loading procedure, the end of any tubing containing radioactive sources must be positioned and secured in such a way as to minimize the possibility of accidental dislodgment. The patient is observed frequently by nursing personnel to verify that the sources remain in position as loaded for the duration of the treatment period.

I. Before the total prescribed brachytherapy dose has been delivered, an authorized user, or a qualified individual under the supervision of an authorized user, (other than the person who made the original calculations, if possible), shall check the dose calculations. Manual dose calculations should be checked for arithmetic errors; appropriate transfer of data from the written directive, plan of treatment, tables and graphs; appropriate use of nomograms (when applicable) and appropriate use of all pertinent data in the calculations.

Computer generated dose calculations shall be checked by examining the computer printout to verify that the correct data for the patient was used in the calculations (e.g., position of the applicator or sealed sources, number of sources, total source strength, or source loading sequence). Alternatively, the brachytherapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer generated outputs (or vise versa), particular emphasis should be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculations (e.g., manual).

NOTE: If the authorized user determines that delaying treatment in order to perform checks of dose calculation would jeopardized the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations shall be performed within two working days of completion of the brachytherapy treatment.

J. An authorized user must date and sign a written record in the patient's chart after insertion of the brachytherapy source but prior to completion of the procedure. The written record shall include the radionuclide, treatment site, total source strength and exposure time (or equivalently, the total dose).

K. Acceptance testing will be done by a qualified individual on each treatment planning of dose calculating computer program that can be used for brachytherapy dose calculations. Acceptance testing will be performed before the first use of a computer program for brachytherapy dose calculations. A written record shall be kept documenting the results of the acceptance tests.

L. Subsequent to the loading of brachytherapy sources, an authorized user or other qualified individual shall verify that the written directive was followed in terms of the number of sources implanted, the source strengths and the source positions. The treatment time will be reaffirmed at this time. In some instances, the authorized user may determine that radiographic procedures are required to confirm proper source positioning.

M. If any unintended deviation from the written directive is identified, it is evaluated and appropriate action taken. Upon identification of an unintended deviation, whether a recordable event or a misadministration, an investigation of the incident shall be made. The cause of the incident shall be determined and, if appropriate, corrective procedures

will be implemented. Documenting and reporting of the unintended deviation shall be in accordance with the reporting rules of 902 KAR 100:073, Section 12.

N. An annual review shall be conducted by the radiation safety officer or by quality management personnel. Using pre-established criteria, the review shall determine the effectiveness of this quality management program. Areas identified as inadequate as determined by failure to meet 100% compliance shall be modified to meet the objectives of 902 KAR 100:073, Section 9. Records of each review, including the evaluations and findings in an auditable form are to be saved for three years. These records may be reviewed by the appropriate regulatory agencies.

O. Review protocol:

Frequency: A review of the quality management program shall be conducted at 12 month intervals with the written summary report presented to the radiation safety committee.

Scope: The review shall evaluate 100% compliance with the following criteria:

1. Having written directives prior to administration of brachytherapy dose.
2. Oral directives are reserved for emergent situations where delay would jeopardize the patient's health.
3. The content of the written directive is as required.
4. All individuals involved in the preparation or administration of brachytherapy doses have received instruction in the requirements of this quality management program and documentation of the training is available.
5. More than one method of verifying the patient's identity is performed prior to administration of the radiopharmaceutical.
6. Brachytherapy dose administrations are in accordance with the specific information contained in the written directive.
7. Unintended deviations from the written directive are identified, evaluated, and appropriate corrective actions instituted.
8. Each recordable event evokes the proper response.
9. Appropriate persons (e.g. authorized user and referring physician) notified and misadministrations reported.
10. Appropriate records kept, including the annual reviews, written directives, brachytherapy doses, recordable events, and misadministrations.

J. Procedures specified in this document will be implemented prior to administration of any brachytherapy doses to patients.

EXHIBIT 3

Radioactive Spill Report

The spill occurred at ___:___ am pm on ___/___/____ in room _____.

Instrument used to check for personnel contamination:

Meter model:_____ Meter SN: _____ Probe model: _____ Probe SN:_____

Personnel present	Personnel contamination results*
_____	_____
_____	_____
_____	_____
_____	_____

* On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a post cleaning contamination wipe-test.

Radioisotopes present or suspected in the spill:

____mCi of _____ as _____

____mCi of _____ as _____

____mCi of _____ as _____

Give a brief description of the accident: _____
_____
_____
_____

Give a brief description of follow up actions taken to prevent recurrence:
_____
_____
_____

Name: _____ Date: _____

EXHIBIT 4

Radioactive Spill Contamination Survey

The spill occurred at ___:___ am/pm on ___/___/____ in room _____.

Decontamination completed at ___:___ am/pm

LOCATION	PRE-CLEAN (mR/hr)	POST CLEAN (mR/hr)	dpm/100 cm^2

Name:_____

EXHIBIT 5

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P. O. No._____ Survey Date _____ Time_____

   Surveyor_____

2. CONDITION OF PACKAGE:

   _____ OK _____Punctured _____Status _____Wet

   _____Crushed _____Other

3. RADIATION UNITS OF LABEL: _____ Units (mR/hr)

4. MEASURED RADIATION LEVELS:

   a. Package surface _____ mR/hr

5. DO PACKING SLIP AND VIAL CONTENTS AGREE:

   a. Radionuclide _____ yes _____ no, difference_____

   b. Amount _____ yes _____ no, difference_____

   c. Chem Form _____ yes _____ no, difference_____

6. WIPE RESULTS FROM:

   a. Outer _____CPM = _____DPM

      eff = ( )

   b. Final source container _____CPM = _____DPM

7. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____mR/hr, CPM

8. DISPOSITION OF PACKAGE AFTER INSPECTION _____

9. SURVEY METER _____

10. INSTRUMENT USE TO COUNT WIPES _____

11. IF CABINET FOR HEALTH SERVICES/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSON NOTIFIED.

Signature_____ Date_____

EXHIBIT 6
NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH
PHOSPHORUS-32, GOLD-198, OR IODINE-131

Patient's Name: _____Date _____

Room No._____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____Method of Administration: _____

	Exposure Rates in mR/hr	
Date	3 feet from bed	10 feet from bed

Comply with all checked items:

____ 1. Visiting time permitted: _____
____ 2. Visitors must remain _____ from patient.
____ 3. Patient may not leave room.
____ 4. Visitors under 18 are not permitted.
____ 5. Pregnant visitors are not permitted.
____ 6. Film or TLD badges must be worn.
____ 7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.
____ 8. Tag the following objects and fill out the tag:
door _____chart _____bed _____wrist
____ 9. Disposable gloves must be worn while attending patient.
____ 10. Patient must use disposable utensils**.**
____ 11. All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.
____ 12. Smoking is not permitted.
____ 13. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.
____ 14. Other instructions.

In case of an emergency contact:
RSO_____
Name On-duty/Off-duty Telephone Numbers

EXHIBIT 7

RADIATION SAFETY CHECKLIST FOR IODINE THERAPY OVER 33 MILLICURIES

Patient: _____Room: _____Date _____

PREPARATION

____ Schedule a private room, with private sanitary facilities and without carpet, in a low traffic area.
____ Cover large room surfaces with absorbent paper and small surfaces with absorbent paper or plastic bags.
____ Prepare labeled boxes for used linen, disposable waste, and non-disposable contaminated items.
____ Prepare urine collection containers if urine will be collected.
____ Stock room with disposable gloves, absorbent paper, and "radioactive waste" labels.
____ Mark a visitors' "safe line" on the floor.
____ Order disposable table service.
____ Notify housekeeping to not clean the room until further notice.
____ Brief the nursing staff on radiation safety measures.
____ Supply the nursing staff with personnel radiation dosimeters.

ADMINISTRATION

____ Clear the room of unneeded personnel.
____ Brief the patient on the clinical procedure.
____ Administer the dosage.
____ Measure dose rates at bedside, 1 meter from bedside, visitors' "safe line," and surrounding hallways and rooms.
____ Post the room with a "Radioactive Materials" sign.

FOLLOW-UP

____ Measure the thyroid burden of all personnel who were present for the administration.
____ Pick up waste for decay-in-storage or decontamination.
____ Release the patient.
____ Decontaminate and survey the room. Remove the "Radioactive Materials" sign.
____ Call the Housekeeping Office to clean the room.

EXHIBIT 8

RADIATION SAFETY CHECKLIST FOR
TEMPORARY IMPLANT THERAPY

Patient: _____ Room_____ Date: _____

PREPARATION

____ Schedule a private room in a low traffic area.

____ Mark a visitors' "safe line" on the floor.

____ Brief the nursing staff on radiation safety measures.

____ Supply the nursing staff with personnel radiation dosimeters.

IMPLANT

____ Clear the room of unneeded personnel.

____ Brief the patient on the clinical procedure.

____ Insert the implant.

____ Measure dose rates at bedside, 1 meter from bedside, visitors" "safe line," and surrounding hallways and rooms.

____ Post the room with a "Radioactive Materials" sign.

FOLLOW-UP

____ Make a radiation survey of the patient to assure that all sources have been removed.

____ Count the number of sources removed from the patient to assure that all sources have been removed.

____ Remove the "Radioactive Materials" sign.

EXHIBIT 9

NURSING INSTRUCTIONS FOR PATIENTS TREATED
WITH TEMPORARY IMPLANT SOURCES

Patient's Name: _____
Phone: _____
Patient Number: _____
Pager:_____Patient Room:_____
Dose:_____mCi of_____as_____individual sources was loaded on ___/___/_____.
am
Sources will be removed at approximately __:__pm on ___/___/_____.

RADIATION EXPOSURE RATES

Unrestricted areas: Door_____mR/hr; room_____--_____mR/hr; room_____--____mR/hr

Patient supine in bed or _____

Date	Time	Bedside	3 ft from bed	Door_____
	am			
___/___/____	__:__pm	_____mR/hr	_____mR/h	_____mR/hr ____mR/hr

Release certification: Patient may not be released from the hospital until the following certification is signed and dated by the RSO or the attending physician.

I have removed and counted _____ individual sources from this patient. A low-range GM survey of the patient failed to indicate any remaining sources in the patient.

Signature: _____Date___/___/_____

INSTRUCTIONS

Visitor Restrictions:

____ No visitors under 18 or pregnant.
____ Minutes each day maximum for each visitor.
____ Visitors must stay behind line on floor at all times.

Nursing Restrictions:
____ Patient is restricted to room.
____ Patient is restricted to bed.
____ Patient must not move.
____ No nurses who are pregnant may render care.
____ Minutes each day per nurse in the room.

Patient Care:

____ Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do Not share. Call RSO for additional monitors if needed.
____ If a source appears dislodged, call the attending physician and the RSO immediately.
____ Omit bed bath.
____ No perineal care. Pad may be changed as necessary.
____ Save surgical dressings for disposal by attending physician or RSO.
____ See special oral hygiene care instructions.

_____
_____
_____

In case of emergency, or if you have a question, call:

RSO: _____ Work:_____ Home:_____
Pager: _____
MD_____ Work:_____ Home:_____
Pager: _____

EXHIBIT 11

ANNUAL MEDICAL LICENSEE RADIOACTIVE MATERIAL PROGRAM AUDIT FOR NUCLEAR MEDICINE

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

Date of this audit:_____ Date of last audit:_____

Auditor: _____ Date:_____

Management review: _____ Date: _____

AUDIT HISTORY

A. Were previous audits conducted annually (100:019, Sec 2)? ( )Y ( ) N

B. Were records of previous audits maintained for 3 years (100:019, Sec 2)? ( )Y ( ) N

C. Were any deficiencies identified during previous audits? ( )Y ( ) N

Deficiencies noted: _____

_____

_____

D. Were corrective actions taken? (Look for repeated deficiencies) ( )Y ( ) N

ORGANIZATION AND SCOPE OF PROGRAM

A. Radiation Safety Officer

1. If the RSO was changed, was license amended (100:073, Sec 2)? ( )Y ( ) N

2. Does new RSO meet training requirements (100:073, Sec 47 or 48)? ( )Y ( ) N

3. Is RSO fulfilling his/her duties (100:073, Sec 5)? ( )Y ( ) N

B. All users authorized by the license (license condition)? ( )Y ( ) N

C. Cabinet for Health Services notified within 30 days of permanent discontinued performance of duties under the license for the RSO, authorized user, teletherapy physics, or authorized nuclear pharmacist (100:073, Sec 3)? ( )Y ( ) N

D. Are all locations of use listed on license (license condition)? ( )Y ( ) N

E. If places of use changed, was the license amended (100:073, Sec 2)? ( )Y ( ) N

F. If control of license was transferred or bankruptcy filed, was Cabinet prior consent obtained or notification made (100:040, Sec 11)? ( )Y ( ) N

QUALITY MANAGEMENT PROGRAM (QMP) (100:073, Sec 9)

A. Are quantities greater than 30 μCi of either sodium iodine I-125 or I-131 administered? ( )Y ( ) N

B. If yes:

1. Has a written QMP been established? ( )Y ( ) N
2. Has the annual review of the QMP been performed? ( )Y ( ) N
3. Records of each review maintained in an auditable form for 3 years? ( )Y ( ) N

RADIATION SAFETY COMMITTEE (RSC) (100:073, Sec 6)

A. Meet at least once each quarter? ( )Y ( ) N

B. Has required membership of RSO, an authorized user of each type of use permitted by the license, a representative from nursing, and a representative from management? ( )Y ( ) N

C. Quorum present including RSO and management at each meeting? ( )Y ( ) N

D. Reviewed quarterly, the results of personnel monitoring? ( )Y ( ) N

E. Reviewed annually, the radioactive material program? ( )Y ( ) N

F. Records of minutes include:

1. Members present and absent.
2. Summery of deliberations and discussions.
3. Recommended actions and results of all ballots.
4. Documents reviewed, (dosimetry results, annual audit, ect.) ( )Y ( ) N

LICENSED MATERIAL

A. Isotopes, chemical forms, quantity and use as authorized (license condition)? ( )Y ( ) N

B. Calibration and references sources authorized by 100:073, Sec 18? ( )Y ( ) N

C. Is all unsealed material used under 100:073, Sec 29, 31, and 35 obtained from a properly licensed organization AND/OR prepared by a physician user, or an individual under the supervision of an authorized nuclear pharmacist or physician user? ( )Y ( ) N

TRAINING AND INSTRUCTION TO WORKERS

A. Have workers been provided with required instructions (100:0165, Sec 2)? ( )Y ( ) N

B. Is annual retraining performed (license condition)? ( )Y ( ) N

C. Are initial and annual training records maintained for each individual ? ( )Y ( ) N

DOSE CALIBRATOR (100:073, Sec 15)

A. Accuracy, linearity, and geometry dependence performed before initial use, following repair, and relocation of each dose calibrator? ( )Y ( ) N

B. Constancy performed for each day the dose calibrator is used? ( )Y ( ) N

1. Record maintained 3 years and includes:

   a. Model & serial number of dose calibrator?
   b. Identity & calculated activity of check source?
   c. Date of the check?
   d. Activity measured within 10%?
   e. Instrument settings?
   f. Initials of individual performing the check? ( )Y ( ) N

C. Linearity test performed at intervals not to exceed 3 months? ( )Y ( ) N

1. Records maintained 3 years and includes:

   a. Model & serial number of dose calibrator?
   b. Identity & calculated activity of check source?
   c. Date of the test?
   d. Activity measured within 10%?
   e. Signature of individual performing the test? ( )Y ( ) N

2. Linearity performed from 30 μCi to highest dose administered? ( )Y ( ) N

D. Accuracy test performed at intervals not to exceed 12 months? ( )Y ( ) N

1. Record maintained 3 years and includes:

   a. Model & serial number of dose calibrator?
   b. Model & serial number for each source?
   c. Date of the test?
   d. Results within 10%?
   e. Instrument settings?
   f. Signature of individual performing the test? ( )Y ( ) N

E. Geometry test record maintained until dose calibrator no longer used and includes:

1. Model & serial number of dose calibrator?
2. Configuration & calibrated activity of the source measured?
3. Date of the test?
4. Activity of the source measured within 10%?
5. Measured activity & instrument setting for each volume measured?
6. Signature of individual performing the test? ( )Y ( ) N

F. Dose calibrator repaired or replaced if accuracy or constancy error exceeds 10%? ( )Y ( ) N

G. Dosage readings mathematically corrected for geometry or linearity errors <10%? ( )Y ( ) N

ASSAY OF RADIOPHARMACEUTICAL DOSES (100:073, Sec 17)

A. Each photon-emitting dose assayed and recorded prior to medical use? ( )Y ( ) N

B. Each alpha or beta emitting dose assayed or obtained in unit dose form, calibrated by a supplier who participates in measurement quality assurance program with the National Institute of Standards and Technology? ( )Y ( ) N

C. Records maintained 3 years and include:

1. Radiopharmaceutical?
2. Lot number?
3. Expiration date?
4. Radionuclide?
5. Patient's name?
6. Prescribed dosage?
7. Activity at time of assay?
8. Date and time of assay?
9. Initials of person who performed assay? ( )Y ( ) N

GENERATORS (100:073, Sec 32)

A. Each elute or extract tested for Mo-99 breakthrough? ( )Y ( ) N

B. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 μCi per mCi of Tc-99m? ( )Y ( ) N

C. Records maintained and include required information? ( )Y ( ) N

D. Reported each occurrence of contamination concentration exceeding limits? ( )Y ( ) N

E. Receipt, transfer, and disposal records for each generator maintained? ( )Y ( ) N

F. Columns held for decay for 10 half lives before disposal? ( )Y ( ) N

G. If generators are returned to vender, are DOT requirements met? ( )Y ( ) N

RADIATION PROTECTION

A. Safe use of radiopharmaceuticals (license condition):

1. Protective clothing and gloves worn? ( )Y ( ) N
2. No eating or drinking in use and storage areas? ( )Y ( ) N
3. Proper dosimetry worn? ( )Y ( ) N
4. Radioactive waste disposed in proper receptacles? ( )Y ( ) N
5. Remote handling devices (tongs) available and used? ( )Y ( ) N
6. Syringe shields and vial shields used? ( )Y ( ) N

B. Leak tests and inventories (100:073, Sec 19):

1. Leak test performed on sealed sources at intervals not to exceed 6 months? ( )Y ( ) N

2. Leak test records maintained 5 years and includes:

   a. Model & serial number of each source?
   b. Identity of each source radionuclide?
   c. Estimated activity of each source?
   d. Measured activity expressed in μCi?
   e. Date of test?
   f. RSO signature? ( )Y ( ) N

3. Inventory of sealed sources performed at intervals not to exceed 3 months? ( )Y ( ) N

4. Inventory records maintained 5 years and include:

   a. Model and serial number of each source?
   b. Identity of each source radionuclide?
   c. Estimated activity of each source?
   d. Location of each source?
   e. Date of inventory?
   f. RSO signature? ( )Y ( ) N

RADIATION SURVEY INSTRUMENTS (100:073, Sec 16)

A. Survey instruments used to show compliance with 100:019 and 100:073? ( )Y ( ) N

B. Appropriate survey instruments possessed (100:073, Sec 34)? ( )Y ( ) N

C. Survey instruments calibrated before use, annually, and after repairs (100:073, Sec 16)? ( )Y ( ) N

D. Dedicated check source reading noted on survey instruments (100:073, Sec 16)? ( )Y ( ) N

RADIATION SURVEYS (100:073, Sec 24)

A. Instrument survey performed daily where radiopharmaceuticals are prepared or administered and weekly where radiopharmaceuticals and waste are stored? ( )Y ( ) N

1. Records maintained for 3 years and includes:

   a. Date of survey?
   b. Sketch of area surveyed?
   c. Established action level?
   d. Measured dose rate in mR/hr?
   e. Model & serial number of survey instrument?
   f. Initials of person who performed the survey? ( )Y ( ) N

B. Weekly wipes in areas where radiopharmaceuticals are routinely prepared, administered, or stored? ( )Y ( ) N

1. Records are maintained for 3 years and includes:

   a. Date of survey?
   b. Sketch of area surveyed?
   c. Established action level?
   d. Removable contamination expressed in dpm/100 cm^2 ?
   e. Model & serial number of instrument used to count wipes?
   f. Initials of person who performed the survey? ( )Y ( ) N

C. Corrective action taken and documented if trigger level is exceeded? ( )Y ( ) N

D. Techniques can detect 0.1 mR/hr; 2000 dpm per 100 cm^2? ( )Y ( ) N

E. Instrument surveys performed quarterly in sealed sources storage area? ( )Y ( ) N

PUBLIC DOSE (100:019)

A. Licensed material used and stored in a manner to keep doses below 100 mRem in a year (100:019, Sec 10)? ( )Y ( ) N

B. Have surveys or evaluations been performed per 100:019, Sec 11? ( )Y ( ) N

C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation? ( )Y ( ) N

D. Do unrestricted area radiation levels exceed 2 mRem in any one hour? ( )Y ( ) N

E. Licensed material used or stored in a manner that would prevent unauthorized access or removal (100:019, Sec 21 & 22)? ( )Y ( ) N

F. Records maintained and include required information (100:019, Sec 31)? ( )Y ( ) N

RADIOACTIVE WASTE

A. Decay-in-storage (100:073, Sec 28)

1. Waste held for 10 half-lives? ( )Y ( ) N

2. Labels removed or defaced? ( )Y ( ) N

3. Monitored at surface of container before disposal as ordinary trash? ( )Y ( ) N

4. Records maintained for 3 years and includes:

   a. Date of the disposal?
   b. Date waste was put in storage?
   c. Radionuclide disposed?
   d. Model & serial number of survey instrument used?
   e. Background dose rate?
   f. Dose rate measured at the surface of each container?
   g. Name of individual performing the disposal? ( )Y ( ) N

B. Waste storage

1. Protected from elements and fire? ( )Y ( ) N

2. Control of waste maintained (100:019, Sec 21)? ( )Y ( ) N

3. Containers properly labeled and area properly posted (100:019, Sec 24 & 26)? ( )Y ( ) N

4. Package integrity adequately maintained? ( )Y ( ) N

C. Waste disposal

1. Waste transferred to authorized individuals (100:021, Sec 1)? ( )Y ( ) N

2. Name of organization: _____

3. Records maintained (100;021, Sec 11)? ( )Y ( ) N

RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

A. Written package opening procedures established and followed (100:019, Sec 28)? ( )Y ( ) N

B. All incoming packages with a DOT label wiped, unless exempt (100:019, Sec 28)? ( )Y ( ) N

C. Incoming packages surveyed (100:019, Sec 28)? ( )Y ( ) N

D. Records maintained and include required information (100:040, Sec 14)? ( )Y ( ) N

E. Transfer(s) performed per 100:040, Sec 12? ( )Y ( ) N

F. All radioactive material surveyed before shipping or transfer (100:070, Sec 14)? ( )Y ( ) N

G. Records of surveys and receipt/transfer maintained (100:019, Sec 31, 100:070, Sec 16)? ( )Y ( ) N

H. Package receipt/distribution activities evaluated for compliance with 100:019, Sec 11? ( )Y ( ) N

TRANSPORTATION (100:070 and Code of Federal Regulations, parts 171-189)

A. Returned radiopharmacy doses or sealed sources? ( )Y ( ) N

1. Licensee assumes shipping responsibilities? ( )Y ( ) N

2. If NO, is the arrangements made between licensee and radiopharmacy for shipping responsibilities on file? ( )Y ( ) N

POSTING AND LABELING

A. Kentucky Form KR-441, "Notice to Employees" is posted (100:165, Sec 1)? ( )Y ( ) N

B. 902 KAR 100:019 and 100:165, emergency and operating procedures, and license documents are posted, or a notice indicating where documents can be examined is posted (100:165, Sec 1)? ( )Y ( ) N

C. Posting for radiation or high radiation areas (100:019, Sec 24)? ( )Y ( ) N

D. Posting for radioactive material use and storage (100:019, Sec 24)? ( )Y ( ) N

PERSONNEL RADIATION PROTECTION

A. Exposure evaluation performed (100:073, Sec 6)? ( )Y ( ) N

B. ALARA program implemented (100:073, Sec 4)? ( )Y ( ) N

C. External Dosimetry

1. Monitors workers per 100:019, Sec 13? ( )Y ( ) N
2. Supplier _____
3. Exchange frequency _____
4. Supplier NVLAP approved (100:019, Sec 12)? ( )Y ( ) N
5. Dosimeters exchanged at required frequency? ( )Y ( ) N

D. Internal Dosimetry

1. Monitors workers per 100:019, Sec 13? ( )Y ( ) N
2. Monitoring program implemented (including bioassays) (100:073, Sec 37)? ( )Y ( ) N

E. Reports

1. Reviewed by _____ Frequency _____
2. Auditor reviewed personnel monitoring records for period _____ to _____
3. Prior dose determined for individuals (100:019, Sec 32)? ( )Y ( ) N
4. Maximum exposures TEDE _____ Extremity _____
5. Internal and external doses summed (100:019, Sec 19)? ( )Y ( ) N
6. Worker declared her pregnancy in writing during audit period? ( )Y ( ) N
   If yes, in compliance with 100:019, Sec 9 and records maintained? ( )Y ( ) N
7. Records of exposures, surveys, monitoring, and evaluations maintained (100:019, Sec 12 & 34)? ( )Y ( ) N

NOTIFICATION AND REPORTS

A. In compliance with 100:0165, Sec 3, and 100:019, Sec 35, (reports to individuals, public and occupational, monitored to show compliance with 100:019)? ( )Y ( ) N

B. In compliance with 100:019, Sec 28 (theft and loss)? ( )Y ( ) N

C. In compliance with 100:019, Sec 39 (incidents)? ( )Y ( ) N

D. In compliance with 100:019, Sec 40 (overexposures and high radiation levels)? ( )Y ( ) N

MEDICAL MISADMINISTRATION (100;073, Sec 12)

A. If a misadministration has occurred since the last audit, evaluated the incident(s) and procedures for implementing and administering written directives using existing guidance.

1. Event date _____ Information source _____

2. Notifications made to:

a. Cabinet for Health Services ( )Y ( ) N

b. Patient ( )Y ( ) N

c. Referring Physician ( )Y ( ) N

d. In writing / By telephone ( )Y ( ) N

3. Written Reports

a. Submitted to Cabinet for Health Services within 15 days? ( )Y ( ) N

b. Copy to patient within 15 days? ( )Y ( ) N

B. Records maintained? ( )Y ( ) N

C. Recordable events:

1. Investigation performed? ( )Y ( ) N

2. Cause identified? ( )Y ( ) N

3. Corrective action taken? ( )Y ( ) N

AUDITS AND FINDINGS

A. Summary of findings: _____

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B. Corrective and preventive actions: _____

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